Australian Government

Department of Health and Ageing

SCHEDULE OF

PHARMACEUTICAL BENEFITS

This Schedule is also available on the internet at
www.pbs.gov.au

EFFECTIVE
1 June 2012 - 30 June 2012

(ALL PREVIOUS EDITIONS CANCELLED)

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the *National Health Act 1953*. However, at the time of printing, the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislative Instruments website at http://www.frli.gov.au.

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PHARMACEUTICAL BENEFITS

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 May 2012 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$6.42
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.46
	Allowable additional patient charge*	$4.04
Additional Fees (for safety net prices):	Ready-prepared	$1.09
	Extemporaneously-prepared	$1.44
Patient Co-payments:	General	$35.40
	Concessional	$5.80
Safety Net Thresholds:	General	$1363.30
	Concessional	$348.00
Safety Net Card Issue Fee:		$8.88

*The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

SUMMARY OF CHANGES

Additions

Addition – Item

1503D **Glucose Indicator—blood**, Test strips, 100 *(Contour)*

1518X **Glucose Indicator—blood**, Test strips, 100 *(Contour)*

Addition – Brand

9049G *Cadatin 5/10, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-10 mg (base)

9050H *Cadatin 5/20, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-20 mg (base)

9051J *Cadatin 5/40, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-40 mg (base)

9052K *Cadatin 5/80, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-80 mg (base)

9053L *Cadatin 10/10, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-10 mg (base)

9054M *Cadatin 10/20, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-20 mg (base)

9055N *Cadatin 10/40, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-40 mg (base)

9056P *Cadatin 10/80, FZ* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-80 mg (base)

8213G *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 10 mg (as calcium)

8213G *Atorvachol, GM* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Atorvachol, GM* – **Atorvastatin**, Tablet 10 mg (as calcium)

8213G *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 10 mg (as calcium)

8213G *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 10 mg (as calcium)

8213G *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 10 mg (as calcium)

8213G *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 10 mg (as calcium)

8213G *Lorstat 10, AF* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Lorstat 10, AF* – **Atorvastatin**, Tablet 10 mg (as calcium)

8213G *Torvastat 10, QA* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Torvastat 10, QA* – **Atorvastatin**, Tablet 10 mg (as calcium)

8214H *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 20 mg (as calcium)

8214H *Atorvachol, GM* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Atorvachol, GM* – **Atorvastatin**, Tablet 20 mg (as calcium)

8214H *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 20 mg (as calcium)

8214H *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 20 mg (as calcium)

8214H *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 20 mg (as calcium)

8214H *Lorstat 20, AF* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Lorstat 20, AF* – **Atorvastatin**, Tablet 20 mg (as calcium)

8214H *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 20 mg (as calcium)

8214H *Torvastat 20, QA* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Torvastat 20, QA* – **Atorvastatin**, Tablet 20 mg (as calcium)

8215J *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 40 mg (as calcium)

8215J *Atorvachol, GM* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Atorvachol, GM* – **Atorvastatin**, Tablet 40 mg (as calcium)

8215J *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 40 mg (as calcium)

8215J *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 40 mg (as calcium)

8215J *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 40 mg (as calcium)

8215J *Lorstat 40, AF* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Lorstat 40, AF* – **Atorvastatin**, Tablet 40 mg (as calcium)

8215J *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 40 mg (as calcium)

8215J *Torvastat 40, QA* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Torvastat 40, QA* – **Atorvastatin**, Tablet 40 mg (as calcium)

8521L *Atorvachol, GM* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Atorvachol, GM* – **Atorvastatin**, Tablet 80 mg (as calcium)

8521L *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *APO-Atorvastatin, TX* – **Atorvastatin**, Tablet 80 mg (as calcium)

8521L *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Atorvastatin GH, GQ* – **Atorvastatin**, Tablet 80 mg (as calcium)

8521L *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Atorvastatin Sandoz, SZ* – **Atorvastatin**, Tablet 80 mg (as calcium)

8521L *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Chem mart Atorvastatin, CH* – **Atorvastatin**, Tablet 80 mg (as calcium)

8521L *Lorstat 80, AF* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Lorstat 80, AF* – **Atorvastatin**, Tablet 80 mg (as calcium)

8521L *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Terry White Chemists Atorvastatin, TW* – **Atorvastatin**, Tablet 80 mg (as calcium)

8521L *Torvastat 80, QA* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Torvastat 80, QA* – **Atorvastatin**, Tablet 80 mg (as calcium)

8604W *Biso 2.5, WQ* – **Bisoprolol Fumarate**, Tablet 2.5 mg

8605X *Biso 5, WQ* – **Bisoprolol Fumarate**, Tablet 5 mg

8606Y *Biso 10, WQ* – **Bisoprolol Fumarate**, Tablet 10 mg

8255L *Volirop 3.125, DO* – **Carvedilol**, Tablet 3.125 mg

8256M *Volirop 6.25, DO* – **Carvedilol**, Tablet 6.25 mg

8257N *Volirop 12.5, DO* – **Carvedilol**, Tablet 12.5 mg

8258P *Volirop 25, DO* – **Carvedilol**, Tablet 25 mg

1256D *Cefazolin-AFT, AE* – **Cephazolin**, Powder for injection 500 mg

5477G *Cefazolin-AFT, AE* – **Cephazolin**, Powder for injection 500 mg

1257E *Cefazolin-AFT, AE* – **Cephazolin**, Powder for injection 1 g

5478H *Cefazolin-AFT, AE* – **Cephazolin**, Powder for injection 1 g

1312C *Diltiazem Sandoz CD, SZ* – **Diltiazem Hydrochloride**, Capsule 180 mg (controlled delivery)

2848X *Torlemo DT 25, TA* – **Lamotrigine**, Tablet 25 mg

2849Y *Torlemo DT 50, TA* – **Lamotrigine**, Tablet 50 mg

2850B *Torlemo DT 100, TA* – **Lamotrigine**, Tablet 100 mg

2851C *Torlemo DT 200, TA* – **Lamotrigine**, Tablet 200 mg

8649F *Pharmacor Mycophenolate 250, CR* – **Mycophenolate Mofetil**, Capsule 250 mg

9197C *Paroxetine Synthon, ZT* – **Paroxetine**, Tablet 20 mg (as mesilate)

2242B *Roxet 20, DO* – **Paroxetine**, Tablet 20 mg (as hydrochloride)

2013Y *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 5 mg

9241J *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 5 mg

2011W *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 10 mg

9242K *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 10 mg

2012X *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 20 mg

9243L *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 20 mg

8133C *Valaciclovir Pfizer, FZ* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

8134D *Valaciclovir Pfizer, FZ* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

5480K *Valaciclovir Pfizer, FZ* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

8064K *Valaciclovir Pfizer, FZ* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

Addition – Equivalence Indicator

9049G *Caduet 5/10, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-10 mg (base)

9050H *Caduet 5/20, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-20 mg (base)

9051J *Caduet 5/40, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-40 mg (base)

9052K *Caduet 5/80, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 5 mg (base)-80 mg (base)

9053L *Caduet 10/10, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-10 mg (base)

9054M *Caduet 10/20, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-20 mg (base)

9055N *Caduet 10/40, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-40 mg (base)

9056P *Caduet 10/80, PF* – **Amlodipine Besylate with Atorvastatin Calcium**, Tablet 10 mg (base)-80 mg (base)

1256D *Hospira Pty Limited, HH* – **Cephazolin**, Powder for injection 500 mg

5477G *Hospira Pty Limited, HH* – **Cephazolin**, Powder for injection 500 mg

Deletions

Deletion – Item

1878W **Amoxycillin**, Sachet containing oral powder 3 g *(Amoxil)*

3309E **Amoxycillin**, Sachet containing oral powder 3 g *(Amoxil)* **(Dental)**

Deletion – Brand

8179L *Anastrozole LW, TA* – **Anastrozole**, Tablet 1 mg

8255L *Dilasig 3.125, FM* – **Carvedilol**, Tablet 3.125 mg

8256M *Dilasig 6.25, FM* – **Carvedilol**, Tablet 6.25 mg

8257N *Dilasig 12.5, FM* – **Carvedilol**, Tablet 12.5 mg

8258P *Dilasig 25, FM* – **Carvedilol**, Tablet 25 mg

1471K *Fluzole 50, QA* – **Fluconazole**, Capsule 50 mg

1182F *Fosinopril Sandoz, SZ* – **Fosinopril Sodium**, Tablet 10 mg

1183G *Fosinopril Sandoz, SZ* – **Fosinopril Sodium**, Tablet 20 mg

8400D *Fosinopril/HCT Sandoz 10mg/12.5mg, SZ* – **Fosinopril Sodium with Hydrochlorothiazide**, Tablet 10 mg-12.5 mg

8401E *Fosinopril/HCT Sandoz 20mg/12.5mg, SZ* – **Fosinopril Sodium with Hydrochlorothiazide**, Tablet 20 mg-12.5 mg

Alterations

Alteration – Manufacturer's Code

		From	*To*
1312C	*Diltahexal CD, HX* – **Diltiazem Hydrochloride**, Capsule 180 mg (controlled delivery)	SZ	HX
2013Y	*Simvahexal, HX* – **Simvastatin**, Tablet 5 mg	SZ	HX
9241J	*Simvahexal, HX* – **Simvastatin**, Tablet 5 mg	SZ	HX
2011W	*Simvahexal, HX* – **Simvastatin**, Tablet 10 mg	SZ	HX
9242K	*Simvahexal, HX* – **Simvastatin**, Tablet 10 mg	SZ	HX
2012X	*Simvahexal, HX* – **Simvastatin**, Tablet 20 mg	SZ	HX
9243L	*Simvahexal, HX* – **Simvastatin**, Tablet 20 mg	SZ	HX

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

1490K **Tenofovir with Emtricitabine and Rilpivirine**, Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride) *(Eviplera)* **(Private)**

1491L **Tenofovir with Emtricitabine and Rilpivirine**, Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride) *(Eviplera)* **(Public)**

Addition – Brand

6208R *Pharmacor Mycophenolate 250, CR* – **Mycophenolate Mofetil**, Capsule 250 mg **(Private)**

9501C *Pharmacor Mycophenolate 250, CR* – **Mycophenolate Mofetil**, Capsule 250 mg **(Public)**

Advance Notices

Advance Notices – Deletion of Item

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 August 2012:
Items discontinued by the manufacturer—

1743R **Oestradiol**, Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 8 *(Estraderm 25)*

Advance Notices – Deletion of Brand

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 August 2012:
Brand discontinued by the manufacturer—

8173E *Simvahexal, HX* – **Simvastatin**, Tablet 40 mg

9244M *Simvahexal, HX* – **Simvastatin**, Tablet 40 mg

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 September 2012:
Brand discontinued by the manufacturer—

1312C *Diltahexal CD, HX* – **Diltiazem Hydrochloride**, Capsule 180 mg (controlled delivery)

2013Y *Simvahexal, HX* – **Simvastatin**, Tablet 5 mg

9241J *Simvahexal, HX* – **Simvastatin**, Tablet 5 mg

2011W *Simvahexal, HX* – **Simvastatin**, Tablet 10 mg

9242K *Simvahexal, HX* – **Simvastatin**, Tablet 10 mg

2012X *Simvahexal, HX* – **Simvastatin**, Tablet 20 mg

9243L *Simvahexal, HX* – **Simvastatin**, Tablet 20 mg

Addresses — Medicare Australia

Medicare Australia has responsibility for the operational aspects of the Pharmaceutical Benefits Scheme (PBS). This responsibility covers the processing of pharmaceutical benefit and safety net claims, authority applications and supply of PBS stationery used by medical practitioners, participating dental practitioners and approved pharmacists.

Procedures for ordering prescription forms are set out in the Introduction of this Schedule.

New South Wales and Australian Capital Territory

Pharmaceutical Benefits Branch
130 George Street
Parramatta NSW 2150
General and IME enquiries — Tel: 132 290

Orange Service Centre
189 Anson Street
Orange NSW 2800
General and IME enquiries — Tel: 132 290

Western Australia

Pharmaceutical Benefits Branch
Level 5, Work Distribution Centre,
(Reception on Level 4)
130 Stirling Street
Northbridge WA 6003
General and IME enquiries — Tel: 132 290

South Australia and Northern Territory

Pharmaceutical Services Branch
209 Greenhill Road
Eastwood SA 5063
General and IME enquiries — Tel: 132 290

Victoria

Pharmaceutical Branch
Level 10
595 Collins Street
Melbourne Vic 3000
General and IME enquiries — Tel: 132 290

Tasmania

Pharmaceutical Branch
199 Collins Street
Hobart Tas 7000
General and IME enquiries — Tel: 132 290

Queensland

Pharmaceutical Services Branch
143 Turbot Street
Brisbane Qld 4000
General and IME enquiries — Tel: 132 290

National Program Management

Pharmaceutical Benefits Branch
Medicare Australia
134 Reed Street
Tuggeranong ACT 2900
Telephone — (02) 6124 6333
Website — www.medicareaustralia.gov.au Email — pbs@medicareaustralia.gov.au

Authority Prescription Applications

Authority required benefits fall into two categories – *Authority required* and *Authority required (STREAMLINED)*. The process in which an authority PBS prescription can be prescribed will depend on the type of Authority required benefit.

Prior approval is required for Authority required items as well as all requests for increased quantities and/or repeats for any category of PBS item.

Prior approval is not required for Authority required (STREAMLINED) items except if increased quantities and/or repeats are required (see Explanatory Notes for details).

Mail Applications:	REPLY PAID No. 9857 PBS Authorities Section Medicare Australia GPO Box 9857 In your Capital City
Telephone Applications:	Free call 1800 888 333 Australia-wide 24 hour service PBS Authorities Section

For telephone applications please have the following information available:

Patient:	Medicare Number Surname First name Full residential address (including post code)
PBS Authority Prescription Number:	Top right hand side of the handwritten PBS Authority Form
Your Prescriber Number:	Located below your address block on the personalised forms
Drug Information:	PBS item Quantity required and number of repeats Daily dose Disease or purpose information

Requests for Drugs via the Special Access Scheme (SAS)

Requests for individual patient approval to obtain drugs that are available only through the SAS may be directed to a delegate within the Drug Safety and Evaluation Branch, Therapeutic Goods Administration, telephone (02) 6232 8111, facsimile (02) 6232 8112, or by mail to PO Box 100 Woden ACT 2606.

Department of Veterans' Affairs

Details of the approving authority for the Department of Veterans' Affairs are listed at the front of the Repatriation Schedule of Pharmaceutical Benefits.

Telephone Interpreter Service

A 24-hour, seven days a week telephone service is available by contacting 131 450.

The translating service (TIS) can provide immediate assistance over the telephone or arrange for an interpreter to go to a location specified in either city or country areas. The TIS service has access to 2000 professional interpreters, covering over 100 languages and dialects.

Poisons Information Centres

Phone 131 126 from anywhere in Australia — 24 hours — form information and advice on the treatment of poisoning, bites and stings

NSW

The New Children's Hospital
Hawkesbury Road
Westmead NSW 2148
Tel: (02) 9845 3111

VIC

Austin Hospital
Studley Road
Heidelberg VIC 3084
Tel: (03) 9496 4410
www.austin.org.au/poisons

QLD

Pharmacy Department
Royal Children's Hospital
Herston QLD 4029
Tel: 131 126

WA

Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: 131 126

TAS

Tel: 131 126

NT

Tel: 131 126

ACT

Tel: 131 126

Drug Information Centres

NSW

Drug Information Pharmacist
New South Wales Medicines Information Centre
PO Box 766
Darlinghurst NSW 2010
Tel: (02) 8382 2136

OR

Drug Information Pharmacist
Hunter Drug Information Service
Newcastle Mater Misericordiae Hospital
Locked Bag 7
Hunter Regional Mail Centre NSW 2310
Tel: (02) 4921 1278
Tel: (02) 4921 1328

VIC

Drug Information Pharmacist
Austin & Repatriation Medical Centre
Studley Road
Heidelberg Vic 3084
Tel: (03) 9496 5668

OR

Drug Information Pharmacist
Drug Information Centre
Southern Health Care Network
Monash Medical Centre
246 Clayton Road
Clayton Vic 3168
Tel:(03) 9594 2361

QLD

Assistant Director of Pharmacy
Queensland Drug Information Ctr
Royal Brisbane Hospital
E Floor, Block 7
Herston Road
Herston Qld 4029
Tel: (07) 3636 7098
(07) 3636 7599

SA

Drug Information Pharmacist
Royal Adelaide Hospital
North Terrace
Adelaide SA 5000
Tel: (08) 8222 5546

OR

Drug Information Pharmacist
Flinders Medical Centre
Bedford Park SA 5042
Tel: (08) 8204 5301

OR

Drug Information Pharmacist
Queen Elizabeth Hospital
Woodville Road
Woodville SA 5011
Tel: (08) 8222 6777

WA

Drug Information Pharmacist
Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: (08) 9346 2923

TAS

Drug Information Pharmacist
Royal Hobart Hospital
GPO Box 1061L
Hobart Tas 7001
Tel: (03) 6222 8737

NT

Drug Information Pharmacist
Royal Darwin Hospital
PO Box 41326
Casuarina NT 0811
Tel: (08) 8922 8424

ACT

Drug Information Pharmacist
Canberra Hospital
Yamba Drive
Garran ACT 2605
Tel: (02) 6244 3333

List of Contact Officers for Recalls of Therapeutic Goods

For details of consumer level recalls only — telephone 1800 020 512

These officers may be contacted —

- to obtain information about current recalls
- to report suspected problems relating to the quality, safety or efficacy of a therapeutic good

Australian Recall Coordinator

Mr Mick O'Connor

Bh 02 6232 8197
Mobile 0421 583 361
Fax 02 6203 1451
E-mail recalls@tga.gov.au

Australian Capital Territory

Mr Michael Conroy

Bh 02 6207 3974
Mobile 0418 182 375
Fax 02 6205 0997
E-mail pharmaceuticalservices@act.gov.au
MichaelJ.Conroy@act.gov.au

New South Wales

Mr B. Battye
Bh 02 9879 3214
Mobile 0401 712 050
Fax 02 9859 5165
E-mail bruce.battye@doh.health.nsw.gov.au
Ms J. Mackson
Bh 02 9879 3214
Mobile 0411 145 562
Fax 02 9859 5165
E-mail jmack@doh.health.nsw.gov.au

Victoria

Ms M. Smith
Bh 03 9096 5355
Bh 1300 364 545
Mobile 0408 598 663
Fax 1300 360 830
E-mail megan.l.smith@health.vic.gov.au
Mr M. McCrone
Bh 03 9096 5066
Bh 1300 364 545
Mobile 0408 581 312
Fax 1300 360 830
E-mail matthew.mccrone@health.vic.gov.au

Queensland

Mr C.J. Healey
Bh 07 3328 9310

Mobile 0403 053 090
Fax 07 3328 9354
E-mail chris_healey@health.qld.gov.au
Mr A. Hawkins
Bh 07 3328 9310
Mobile 0449 267 625
Fax 07 3228 9354
E-mail andrew_hawkins@health.qld.gov.au

South Australia

Mr S. Morris
Bh 08 8204 1940
Mobile 0431 657 090
Fax 08 8226 9837
E-mail steve.morris@health.sa.gov.au
Ms E. Hender
Bh 0418 747 833
Mobile 0431 657 090
Fax 08 8226 9837
E-mail elizabeth.hender@health.sa.gov.au

Western Australia

Mr Neil Keen
Bh 08 9222 6883

Mobile 0419 944 801
Fax 08 9222 2463
E-mail neil.keen@health.wa.gov.au
poisons@health.wa.gov.au

Tasmania

Ms M. Sharpe
Bh 03 6233 3766

Ah 03 6223 3476
Fax 03 6233 3904
E-mail mary.sharpe@dhhs.tas.gov.au
Mr J. Galloway
Bh 03 6233 2064

Ah 03 6223 7074
Fax 03 6233 3904
E-mail james.galloway@dhhs.tas.gov.au

Northern Territory

Ms Helgi Stone
Bh 08 8922 7035

Mobile 0429 091 636
Fax 08 8922 7200
E-mail Helgi.stone@nt.gov.au
Mr T. DeZilva
Bh 08 8922 7340
Mobile 0400 251 419
Fax 08 8922 7200
E-mail tyronne.dezilva@nt.gov.au

Index of Manufacturers' Codes

Code	*Manufacturer*
AB	Abbott Australasia Pty Ltd Sir Joseph Banks Corporate Park 32-34 Lord Street Botany NSW 2019 Tel: (02) 9384 9700 Fax: (02) 9384 9800
AC	Alberto Culver Company 14 Loyalty Road North Rocks NSW 2151 Tel: (02) 9630 5099 Fax: (02) 9683 5026
AE	AFT Pharmaceuticals Pty Ltd Level 1, 296 Burns Bay Road Lane Cove NSW 2066 Tel: 1800 097 639 Fax: 1800 097 810
AF	Alphapharm Pty Limited Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 Tel: (02) 9298 3999 Fax: (02) 9566 4686
AG	Allergan Australia Pty Ltd Level 4, 810 Pacific Highway Gordon NSW 2072 Tel: 1800 252 224 Fax: (02) 9498 0290
AL	Alphapharm Medical A Division of Alphapharm Pty Limited Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 Tel: (02) 9298 3999 Fax: (02) 9566 4686
AN	Amgen Australia Pty Ltd Level 7, 123 Epping Road North Ryde NSW 2113 Tel: (02) 9870 1333 Fax: (02) 9870 1344
AO	Advanced Medical Optics Australia Pty Ltd Level 3, Building 2 20 Bridge Street Pymble NSW 2073 Tel: 1800 266 111 Fax: 1800 266 222
AP	AstraZeneca Pty Ltd Alma Road North Ryde NSW 2113 Tel: (02) 9978 3500 Fax: (02) 9978 3700
AQ	Alcon Laboratories (Australia) Pty Ltd Allambie Grove Park 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: 1800 025 004 Fax: (02) 9452 5209
AS	Aspen Pharmacare Australia Pty Ltd First Floor, 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
AT	Actelion Pharmaceuticals Australia Pty Ltd Level 2 West, Suites 48-50 7 Narabang Way Belrose NSW 2085 Tel: (02) 9486 4600 Fax: (02) 9986 1344
AV	Aventis Pharma Division of Sanofi-Aventis Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
BB	Blackmores Ltd 23 Roseberry Street Balgowlah NSW 2093 Tel: (02) 9951 0111 Fax: (02) 9949 1954
BD	Biogen Idec Australia Pty Ltd Suite 2, Level 4 123 Epping Road North Ryde NSW 2113 Tel: (02) 8875 3900 Fax: (02) 9889 1162
BE	Beiersdorf Australia Limited 4 Khartoum Road North Ryde NSW 2113 Tel: (02) 9888 0977 Fax: (02) 9887 3487
BF	Bellwether Pharma Ltd Suite 1, Level 1 1175 Toorak Road Camberwell Vic 3124 Tel: (03) 9809 7900 Fax: (03) 9809 7999
BG	Biochemie Australia A Division of Sandoz Pty Ltd Level 2, 19 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
BI	Biotech Pharmaceuticals Pty Ltd 83 Cherry Lane Laverton North Vic 3026 Tel: (03) 9278 7555 Fax: (03) 9369 6730
BK	Becton Dickinson Pty Ltd 80 Rushdale Street Knoxfield Vic 3180 Tel: (03) 9764 2444 Fax: (03) 9764 2550
BN	Bayer Australia Limited 875 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311

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Code	Manufacturer
BQ	Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd 556 Princes Highway Noble Park Vic 3174 Tel: (03) 9213 4000 Fax: (03) 9701 1518
BR	B. Braun Australia Pty Ltd Norwest Business Park 17 Lexington Drive Bella Vista NSW 2153 Tel: (02) 9629 0200 Fax: (02) 9629 0299
BU	Bausch & Lomb Surgical A Division of Bausch & Lomb (Australia) Pty Ltd Level 4, 113 Wicks Road North Ryde NSW 2113 Tel: (02) 9887 1444 Fax: (02) 9888 9642
BV	B.S.N. 315 Ferntree Gully Road Mount Waverley Vic 3149 Tel: (03) 8540 6777 Fax: 1800 671 000
BX	Baxter Healthcare Pty Limited 1 Baxter Drive Old Toongabbie NSW 2146 Tel: (02) 9848 1111 Fax: (02) 9848 1123
BY	Boehringer Ingelheim Pty Limited 78 Waterloo Road North Ryde NSW 2113 Tel: (02) 8875 8800 Fax: (02) 8875 8801
BZ	Boucher & Muir Pty Ltd trading as BNM Group Level 1, 134 Willoughby Road Crows Nest NSW 2065 Tel: (02) 9431 6333 Fax: (02) 9906 7147
CC	ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd 606 Hawthorn Road East Brighton Vic 3187 Tel: 1800 335 276 Fax: (03) 9525 0920
CH	Symbion Pty Ltd, trading as Chemmart Level 3, 484 St Kilda Road Melbourne Vic 3004 Tel: (03) 9918 5555 Fax:
CJ	Celgene Pty Ltd Level 7, 607 St Kilda Road Melbourne Vic 3004 Tel: (03) 9539 5500 Fax: (03) 9539 5566
CR	Pharmacor Limited 5/36 Campbell Avenue Cromer NSW 2099 Tel: (02) 9981 4470 Fax: (02) 9981 4475
CS	CSL Limited 45 Poplar Road Parkville Vic 3052 Tel: (03) 9389 1911 Fax: (03) 9388 2351
CT	Coloplast Pty Ltd 33 Gilby Road Mount Waverley Vic 3149 Tel: 1800 673 317 Fax: (03) 9541 1199
CU	Care Pharmaceuticals Pty Ltd Suite 303, Level 3, 59-75 Grafton Street Bondi Junction NSW 2022 Tel: 1800 788 870 Fax:
CX	Contact Lens Centre Australia Pty Ltd Unit D6, Hallmark Business Park Cnr Westall and Centre Roads Clayton Vic 3168 Tel: (03) 9543 1811 Fax: (03) 9543 8066
DO	Aurobindo Pharma (Australia) Pty Ltd Unit 3, North Rydelink Business Park 277-283 Lane Cove Road Macquarie Park NSW 2113 Tel: (02) 9805 6000 Fax: (02) 9887 1191
DQ	Church & Dwight (Australia) Pty Ltd Unit 1/108 Old Pittwater Road Brookvale NSW 2100 Tel: 1800 222 099 Fax:
EH	Entra Health Systems Pty Ltd 12/60 Castlereagh Street Sydney NSW 2000 Tel: (02) 8005 4745 Fax: (02) 8088 7105
EL	Eli Lilly Australia Pty Limited 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444 Fax: (02) 9325 4410
EO	Ego Pharmaceuticals Pty Ltd 21-31 Malcolm Road Braeside Vic 3195 Tel: (03) 9587 1088 Fax: (03) 9580 7647
FB	Pierre Fabre Medicament Australia Pty Limited Suite 3B, 1 Richardson Place North Ryde NSW 2113 Tel: (02) 8662 9800 Fax: (02) 8662 9888

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Code	Manufacturer
FK	Invida Australia Pty Ltd Level 8, 67 Albert Avenue Chatswood NSW 2067 Tel: (02) 9080 7200 Fax: (02) 9080 7201
FM	Fawns and McAllan Pty Ltd A member of Aspen Group of Companies 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2802
FP	Ferring Pharmaceuticals Pty Ltd Suite 2, Level 1, Building 1 Pymble Corporate Centre 20 Bridge Street Pymble NSW 2073 Tel: (02) 9497 2300 Fax: (02) 9497 2399
FR	Charles E. Frosst Division of Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
FZ	Pfizer Established Products Division of Pfizer Australia Pty Ltd 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9850 3111
GA	Galderma Australia Pty Ltd Suite 4, 13B Narabang Way Belrose NSW 2085 Tel: (02) 9479 0600 Fax: (02) 9986 1699
GC	GlaxoSmithKline Consumer Healthcare 82 Hughes Avenue Ermington NSW 2115 Tel: (02) 9684 0888 Fax: (02) 9684 6958
GH	Goldshield Healthcare (Australia) Pty Ltd Level 1, 134 Willoughby Road Crows Nest NSW 2065 Tel: (02) 9431 6333 Fax: (02) 9906 7147
GI	Gilead Sciences Pty Ltd Level 1, 128 Jolimont Road East Melbourne Vic 3002 Tel: (03) 9272 4400 Fax: (03) 9272 4435
GK	GlaxoSmithKline Australia Pty Ltd Level 4, 436-438 Johnston Street Abbotsford Vic 3067 Tel: (03) 9413 7300 Fax: (03) 8761 2410
GM	Ascent Pharma Pty Ltd 151-153 Clarendon Street South Melbourne Vic 3205 Tel: 1800 678 302 Fax: (03) 8677 6666
GN	Ascent Pharmaceuticals Limited 151-153 Clarendon Street South Melbourne Vic 3205 Tel: 1800 678 302 Fax: (03) 8677 6666
GQ	Generic Health Pty Ltd Suite 1, Level 1 1175 Toorak Road Camberwell Vic 3124 Tel: (03) 9809 7900 Fax: (03) 9809 7999
GX	GenRx A Division of Apotex Pty Ltd 16 Giffnock Avenue Macquarie Park NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377
GZ	Genzyme A Division of sanofi-aventis Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
HA	Hamilton Laboratories Pty Ltd 217 Flinders Street Adelaide SA 5000 Tel: (08) 8223 2957 Fax: (08) 8232 1480
HC	Biotech Healthcare A division of Biotech Pharmaceuticals Pty Ltd 83 Cherry Lane Laverton North Vic 3026 Tel: (03) 9278 7555 Fax: (03) 9369 6730
HE	HealthSense Products Pty Ltd 87 Pitfield Crescent Rowville Vic 3178 Tel: 1300 462 188 Fax:
HH	Hospira Pty Ltd (David Bull Laboratories, Faulding Pharmaceuticals) Level 3, 500 Collins Street Melbourne Vic 3000 Tel: (03) 8744 5200 Fax: (03) 9866 3504
HL	Helex-A Pty Ltd 9/7 Anella Avenue Castle Hill NSW 2154 Tel: (02) 9846 1911 Fax: (02) 9846 1930

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Code	Manufacturer
HM	Meda Pharmaceuticals Pty Ltd Level 20, Tower A, The Zenith Centre, 821 Pacific Highway Chatswood NSW 2067 Tel: (02) 8448 2080 Fax: (02) 8448 2010
HR	Paul Hartmann Pty Ltd 27-28/11-21 Underwood Road Homebush NSW 2140 Tel: 1800 805 839 Fax: (02) 8762 7100
HX	Hexal Australia A division of Sandoz Pty Ltd Level 2, 19 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
IA	iNova Pharmaceuticals (Australia) Pty Limited 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333 Fax: (02) 9875 6416
IK	Medtronic Australasia Pty Ltd 97 Waterloo Road North Ryde NSW 2113 Tel: (02) 9857 9000 Fax: (02) 9887 1829
IQ	Ioquin A Division of Alcon Laboratories (Australia) Pty Ltd Allambie Grove Park 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: 1800 025 004 Fax: (02) 9452 5209
IS	Ipsen Pty Ltd Suite 6, 40 Montclair Avenue Glen Waverley Vic 3150 Tel: (03) 8544 8100 Fax: (03) 9562 5152
IX	Clinect Pty Ltd Level 3, 484 St Kilda Road Melbourne VIC 3004 Tel: (03) 9918 5555 Fax: (03) 9918 5582
JC	Janssen-Cilag Pty Ltd 1-5 Khartoum Road North Ryde NSW 2113 Tel: (02) 8875 3333 Fax: (02) 8875 3300
JJ	Johnson & Johnson Medical 1-5 Khartoum Road North Ryde NSW 2113 Tel: (02) 9878 9111 Fax: 1800 808 233
JT	Johnson & Johnson Pacific Pty Limited 45 Jones Street Ultimo NSW 2007 Tel: 13 1565 Fax: (02) 8260 8102
KE	Kendall Australasia Pty Ltd 22 Giffnock Avenue North Ryde NSW 2113 Tel: 1800 252 467 Fax: (02) 9888 7378
KN	Knoll A Division of Abbott Australasia Pty Ltd 32-34 Lord Street Botany NSW 2019 Tel: (02) 9384 9700 Fax: (02) 9384 9800
KP	KwikPen Products of Eli Lilly Australia Pty Limited 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444 Fax: (02) 9325 4410
KY	Key Pharmaceuticals Pty Ltd 12 Lyonpark Road Macquarie Park NSW 2113 Tel: (02) 8113 6200 Fax: (02) 8113 6222
LB	Life Bioscience Pty Ltd 10 Atherton Road Oakleigh Vic 3166 Tel: 1800 114 610 Fax: (03) 8660 2785
LM	Link Medical Products Pty Ltd Unit 1, 5 Apollo Street Warriewood NSW 2102 Tel: (02) 8401 9777 Fax: (02) 8401 9786
LN	Lennon Healthcare A Division of Aspen Pharmacare Australia Pty Ltd First Floor 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
LO	LEO Pharma Pty Ltd Level 3, Tower 1 25 Montpelier Road Bowen Hills Qld 4006 Tel: (07) 3250 1200 Fax: (07) 3250 1299
LU	Lundbeck Australia Pty Ltd 1 Innovation Road North Ryde NSW 2113 Tel: (02) 8669 1000 Fax: (02) 8669 1090
LY	Eli Lilly Australia Pty Limited 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444 Fax: (02) 9325 4410
MD	Macarthur Research Division of Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9981 3229

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Code	Manufacturer
MF	Mundipharma Pty Ltd Level 33, 50 Bridge Street Sydney NSW 2000 Tel: (02) 9231 7200 Fax: (02) 9223 0011
MH	Molnlycke Health Care Pty Ltd Building 1, Ground Floor 14 Aquatic Drive Frenchs Forest NSW 2086 Tel: (02) 9453 1144 Fax: (02) 9453 1155
MI	Meditech Int. Pty Ltd Unit 5, 36 Campbell Avenue Cromer NSW 2099 Tel: (02) 9981 4470 Fax: (02) 9981 4475
MK	Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
MM	3M Pharmaceuticals Australia Pty Ltd 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333 Fax: (02) 9875 6416
MQ	Alphapharm Pharmaceuticals Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 Tel: (02) 9298 3999 Fax: (02) 9566 4686
MS	Abbott Diabetes Care (A Division of Abbott Australasia Pty Ltd) 666 Doncaster Road Doncaster Vic 3108 Tel: (03) 9843 7100 Fax: (03) 9855 8020
MT	Mentholatum Australasia Pty Ltd 12-16 Janine Street Scoresby Vic 3179 Tel: (03) 9763 0322 Fax: (03) 9763 2699
MW	Biomed Aust Pty Ltd c/- Robinson Legal Level 4, 350 Kent Street Sydney NSW 2000 Tel: (02) 9299 2100 Fax: (02) 9299 2201
NA	National Diagnostic Products 22/39 Herbert Street St Leonards NSW 2065 Tel: (02) 9432 8100 Fax: (02) 9432 1151
NC	Novartis Consumer Health Australasia Pty Ltd 327-333 Police Road Mulgrave Vic 3170 Tel: (03) 9701 2711 Fax: (03) 9701 2911
NE	Norgine Pty Limited 3/14 Rodborough Road Frenchs Forest NSW 2086 Tel: (02) 9972 7500 Fax: (02) 9972 7522
NF	FlexPen Products of Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799
NH	Nycomed Healthcare Pty Limited 2 Lyon Park Road Macquarie Park North Ryde NSW 2113 Tel: (02) 9859 6900 Fax: (02) 9859 6950
NI	InnoLet Products of Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799
NM	Novartis Medicines A Division of Novartis Pharmaceuticals Australia Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9805 3555 Fax: (02) 9887 4551
NO	Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799
NQ	Nycomed Pty Ltd 2 Lyon Park Road Macquarie Park North Ryde NSW 2113 Tel: (02) 9859 6900 Fax: (02) 9859 6950
NT	Nestlé Australia Ltd 60 Bathurst Street Sydney NSW 2000 Tel: (02) 9931 2345 Fax: (02) 9931 2610
NU	Nutricia Australia Pty Limited Talavera Corporate Centre Level 4, Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 8875 0300 Fax: (02) 8978 4841
NV	Novartis Pharmaceuticals Australia Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9805 3555 Fax: (02) 9887 4551

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Code	*Manufacturer*
NX	Nipro Australia Pty Ltd Suite 2, 20 Churchill Crescent Cammeray NSW 2062 Tel: 1800 451 737 Fax: (03) 9879 9945
NZ	Nycomed Services Pty Limited 2 Lyon Park Road Macquarie Park North Ryde NSW 2113 Tel: (02) 9859 6900 Fax: (02) 9859 6950
OA	Orphan Australia Pty Ltd A member of Aspen Group of Companies First Floor, 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
OB	Oral B Laboratories Pty Ltd Level 3, 90 Mount Street North Sydney NSW 2060 Tel: (02) 9957 6499 Fax: (02) 9957 5383
OE	Omegapharm Pty Ltd 21 Queen Street Ormond Vic 3204 Tel: (03) 9483 0070 Fax: (03) 9483 0070
OI	Boian Surgical Pty Ltd 486 King Georges Road Beverly Hills NSW 2209 Tel: (02) 9580 7447 Fax: (02) 9580 7450
OL	Owen Laboratories Division of Galderma Australia Pty Ltd 9 Rodborough Road Frenchs Forest NSW 2086 Tel: 1800 800 765 Fax: (02) 9975 5374
OM	Colgate Oral Care 345 George Street Sydney NSW 2000 Tel: (02) 9229 5600 Fax: (02) 9232 8448
ON	Orion Laboratories Pty Ltd 25-29 Delawney Street Balcatta WA 6021 Tel: (08) 9441 7800 Fax: (08) 9441 7888
OY	Orion Laboratories Pty Ltd 25-29 Delawney Street Balcatta WA 6021 Tel: (08) 9441 7800 Fax: (08) 9441 7888
OZ	Medical Specialties Australia Pty Ltd 54 Gibbes Street Chatswood NSW 2067 Tel: (02) 9417 7955 Fax: (02) 9417 5779
PE	Pacific EyeCare A Division of Allergan Australia Pty Ltd Level 4, 810 Pacific Highway Gordon NSW 2072 Tel: 1800 252 224 Fax: (02) 9498 0290
PF	Pfizer Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347
PK	Fresenius Kabi Australia Pty Limited 964 Pacific Highway Pymble NSW 2073 Tel: 1300 732 001 Fax: 1300 304 384
PL	Phebra 332 Burns Bay Road Lane Cove NSW 2066 Tel: (02) 9420 9199 Fax: (02) 9420 9177
PM	PMC Pharma A Division of AstraZeneca Pty Ltd Alma Road North Ryde NSW 2113 Tel: (02) 9978 3500 Fax: (02) 9978 3700
PP	Petrus Pharmaceuticals Pty Ltd Level 3, IBM Building 1060 Hay Street West Perth WA 6005 Tel: (08) 9368 5954 Fax: (08) 9368 6692
PQ	PMIP Pty Ltd Unit 1, 5 Apollo Street Warriewood NSW 2102 Tel: (02) 8401 9777 Fax: (02) 8401 9786
PX	Point of Care Diagnostics Australia Pty Ltd Unit 14, 76 Reserve Road Artarmon NSW 2064 Tel: (02) 9437 1355 Fax: (02) 9437 1399
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd 99 Phillip Street Parramatta NSW 2150 Tel: (02) 9685 4500 Fax: (02) 9685 4777
PZ	Prohealth Asia Pacific Pty Ltd Suite 108A, 20 Lexington Drive Bella Vista NSW 2153 Tel: 1300 024 784 Fax: 1300 008 463

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Code	Manufacturer
QA	Aspen Pharma Pty Ltd 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2802
QB	Bionime Australia Pty Ltd Level 7, 60 York Street Sydney NSW 2000 Tel: (02) 9262 6900 Fax: (02) 9262 6922
QR	Ranbaxy Australia Pty Limited Suite 4.02, Level 4 Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 9647 1172 Fax: (02) 9647 1172
RA	Ranbaxy Australia Pty Limited Suite 4.02, Level 4 Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 9647 1172 Fax: (02) 9647 1172
RB	BioRevive Pty Ltd Level 1, 263 Mary Street Richmond Vic 3121 Tel: (03) 8416 0399 Fax: (03) 8416 0345
RC	Reckitt Benckiser (Australia) Pty Limited 44 Wharf Road West Ryde NSW 2114 Tel: (02) 9857 2000 Fax: (02) 9857 2004
RD	Roche Diagnostics Australia Pty Ltd 31 Victoria Avenue Castle Hill NSW 2154 Tel: (02) 9899 7999 Fax: (02) 9634 4696
RO	Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9971 7401
RX	Ardix A Division of Servier Laboratories (Australia) Pty Ltd 8 Cato Street Hawthorn Vic 3122 Tel: (03) 8823 7333 Fax: (03) 9822 9790
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd Level 1, 181 Bay Street Brighton Vic 3186 Tel: (03) 9595 3812 Fax: (03) 9595 3800
SA	SciGen (Australia) Pty Ltd Suite 1, 13B Narabang Way Belrose NSW 2085 Tel: (02) 9485 1800 Fax: (02) 9485 1888
SB	Nutricia Australia - Clinical A division of Nutricia Australia Pty Limited Talavera Corporate Centre Level 4, Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 8875 0300 Fax: (02) 8978 4841
SE	Servier Laboratories (Aust.) Pty Ltd 8 Cato Street Hawthorn Vic 3122 Tel: (03) 8823 7333 Fax: (03) 9822 9790
SG	Merck Serono Australia Pty Ltd Unit 3-4, 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: (02) 8977 4100 Fax: (02) 9975 1516
SI	Sigma Company Limited 1408 Centre Road Clayton Vic 3168 Tel: (03) 9542 9987 Fax: (03) 9542 9548
SJ	Sharpe Laboratories Pty Ltd 12 Hope Street Ermington NSW 2115 Tel: (02) 9858 5622 Fax: (02) 9858 5957
SN	Smith & Nephew Healthcare 315 Ferntree Gully Road Mount Waverley Vic 3149 Tel: (03) 8540 6777 Fax: 1800 671 000
SS	SSL Australia Pty Ltd 225 Beach Road Mordialloc Vic 3195 Tel: 1800 999 155 Fax: (03) 9587 6870
SW	Sanofi-Aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
SY	Bayer Australia Ltd 875 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311
SZ	Sandoz Pty Ltd Level 2, 19 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
TA	Actavis Australia Pty Ltd Upper Ground Floor 183 Melbourne Street North Adelaide SA 5006 Tel: (08) 8267 1545 Fax: (08) 8267 2642

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Code	*Manufacturer*
TM	Technipro Marketing Pty Ltd Unit 10, 13 Berry Street Clyde NSW 2142 Tel: (02) 9897 5899 Fax: (02) 9897 5799
TS	Specialised Therapeutics Australia Pty Ltd Level 1, 711 High Street Kew East Vic 3102 Tel: 1300 798 820 Fax: 1800 798 829
TW	Symbion Pty Ltd, trading as Terry White Chemists Level 3, 484 St Kilda Road Melbourne Vic 3004 Tel: (03) 9918 5555 Fax:
TX	Apotex Pty Ltd 16 Giffnock Avenue Macquarie Park NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377
UC	UCB Pharma A Division of UCB Australia Pty Ltd Level 1, 1155 Malvern Road Malvern Vic 3144 Tel: (03) 9828 1800 Fax: (03) 9828 1860
UM	Unomedical Pty Ltd 11-17 Wilmette Place Mona Vale NSW 2103 Tel: (02) 9997 8033 Fax: (02) 9997 3760
VF	Vitaflo Australia Pty Ltd 110 Fyans Street South Geelong Vic 3220 Tel: (03) 5229 8222 Fax: (03) 5229 8225
VI	ViiV Healthcare Pty Ltd Level 4, 436-438 Johnston Street Abbotsford Vic 3067 Tel: (03) 9413 7300 Fax: (03) 8761 2456
VP	Meda Valeant Pharma Australia Pty Ltd Level 7, Suite 7.02 3 Rider Boulevard Rhodes NSW 2138 Tel: (02) 8757 5100 Fax: (02) 9743 4053
VT	Valeant Pharmaceuticals Australasia Pty Ltd Level 7, Suite 7.02 3 Rider Boulevard Rhodes NSW 2138 Tel: 1800 630 056 Fax: (02) 9743 4053

Code	*Manufacturer*
WA	Winthrop Pharmaceuticals Division of Sanofi-Aventis Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
WQ	Willow Pharmaceuticals Pty Limited Level 4, 5 Essex Street The Rocks NSW 2000 Tel: (02) 9241 2235 Fax: (02) 9241 2217
XF	Max Pharma Pty Ltd Suite 1, Level 1 1175 Toorak Road Camberwell Vic 3124 Tel: (03) 9809 7900 Fax: (03) 9809 7999
XM	The Medicines Company (Australia) Pty Ltd Suite 1, Level 8, North Tower, 1-5 Railway Street Chatswood NSW 2067 Tel: 1800 755 459 Fax: (02) 9412 4556
XP	Aaxis Pacific Pty Ltd 24-32 Forge Street Blacktown NSW 2148 Tel: (02) 9881 3333 Fax: (02) 9881 3322
XS	Symbion Pty Ltd Level 3, 484 St Kilda Road Melbourne Vic 3004 Tel: (03) 9918 5555 Fax:
YM	Symbion Pty Ltd Level 3, 484 St Kilda Road Melbourne Vic 3004 Tel: (03) 9918 5555 Fax:
YN	Mayne Pharma International Pty Ltd 1538 Main North Road Salisbury SA 5106 Tel: (08) 8209 2666 Fax: (08) 8281 6998
YS	Symbion Pty Ltd Level 3, 484 St Kilda Road Melbourne Vic 3004 Tel: (03) 9918 5555 Fax:
YT	Mayne Products Pty Ltd 1538 Main North Road Salisbury SA 5106 Tel: (08) 8209 2666 Fax: (08) 8281 6998

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Code	*Manufacturer*
ZF	Sun Pharmaceutical Industries (Australia) Pty Ltd 1053 Burwood Highway Ferntree Gully Vic 3156 Tel: (03) 9568 6102 Fax: (03) 9568 6610
ZI	Shire Australia Pty Limited Level 9, Avaya House 123 Epping Road North Ryde NSW 2113 Tel: 1800 012 612 Fax: (02) 8875 7977
ZP	Spirit Pharmaceuticals Pty Ltd 117 Harrington Street The Rocks Sydney NSW 2000 Tel: (02) 9251 1088 Fax: (02) 9251 1099
ZT	Synthon A.U. Pty Ltd Suite 511, 460 Pacific Highway St Leonards NSW 2065 Tel: (02) 9966 9900 Fax: (02) 9966 9099

Code	*Manufacturer*

Section 1 — Explanatory Notes

Introduction

These Explanatory Notes are provided to help PBS prescribers and pharmacists work within the Australian Government's Pharmaceutical Benefits Scheme (PBS).

The PBS is a system of subsidising the cost of most prescription medicines. The subsidies are available to all Australian residents and eligible foreign visitors, i.e., people from countries which have Reciprocal Health Care Agreements with Australia. These countries are the United Kingdom, Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands, Finland, Norway, Belgium and Slovenia.

The aim of the PBS, which has been in operation since 1948, is to provide reliable and affordable access to a wide range of necessary medicines.

The Schedule of Pharmaceutical Benefits referred to throughout as the 'Schedule' – lists all the medicinal products available under the PBS, and explains the uses for which they can be subsidised.

The Schedule is produced monthly by the Australian Department of Health and Ageing (effective on the first day of each month).

It is vital therefore that PBS prescribers and pharmacists remain up to date with information on which medicines are included in or excluded from the Schedule, which PBS prescribers may prescribe certain medicines, whether restrictions apply to the medicines, and how much patients should pay.

Queries relating to the PBS can be made to the Pharmaceutical Benefits Branch of Medicare Australia (telephone 132 290 open 24 hours a day, 7 days a week). Queries relating to the Repatriation Pharmaceutical Benefits Scheme (RPBS) can be made to the State offices of the Department of Veterans' Affairs (DVA) (telephone 1800 552 580).

1. The Schedule — Where to Find What

The Schedule of Pharmaceutical Benefits is divided into sections. At the start of the Schedule, immediately after the table of contents, is a summary of any changes to listed items. This is followed by a list of important information sources, contacts and addresses, then an index of manufacturers' codes.

The last pages of the Schedule provide a generic/proprietary index of PBS and RPBS ready-prepared items.

Section 1

Section 1 is what you are reading, the Explanatory Notes. It outlines the correct way to prescribe and supply pharmaceutical benefits; patient charges; who qualifies for concessions; how the Safety Net system works; and, for pharmacists, how to claim reimbursement for PBS items.

Please note that except where indicated, the term ' **prescriber**' is used in this section to cover doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS medicines under the National Health Act 1953.

And except where stated otherwise, the term ' **pharmacist**' means a pharmacist approved to supply medicines under the PBS.

Section 2

This section lists ready-prepared items, and includes the form, manner of administration, brand and brand equivalents which may be prescribed, and the maximum quantity and number of repeats for each item.

Emergency drug supplies are also listed at the beginning of this section.

Any medicines that have restrictions on how they can be prescribed are printed in ***bold italics*** . Items appearing in more than one therapeutic group are cross-referenced.

The second page of Section 2 explains symbols used throughout the Schedule.

The use of 'NOTE' in this section is used to clarify how some pharmaceutical benefits should be prescribed.

The use of 'CAUTION' is to warn of known adverse reactions from, or precautions to be taken with, a particular pharmaceutical benefit. (The absence of a cautionary note does not imply reactions may not happen.)

Separate lists at the end of Section 2 relate to items that can be prescribed by dentists and optometrists who work within the PBS. These are followed by a list of items that are made available under special arrangements for doctors to prescribe.

Section 3

This section lists container prices, fees related to dispensing, standard packs and prices for ready-prepared preparations.

Section 4

This section deals with extemporaneous preparations. It lists the ingredients which can be used, a table of maximum quantities and number of repeats, container prices, and a list of standard formula preparations and prices (based on formularies in common use and referred to in the Schedule as the Standard Formulae List).

Restrictions applying to the use of a pharmaceutical benefit are indicated against the item.

Repatriation Schedule of Pharmaceutical Benefits

After Section 4, the Schedule provides information about pharmaceutical benefits under the RPBS. These may only be prescribed to DVA beneficiaries holding one of the repatriation health cards (see details under '4. Patient Charges').

2. Prescribing Medicines – Information for PBS Prescribers

PBS prescribers

Pharmaceutical benefits can only be prescribed by doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS medicines under the *National Health Act 1953*.

PBS Prescription forms

Standard PBS prescription forms are available from Medicare Australia for prescribing pharmaceutical benefits.

For doctors:

- *Personalised forms* — are printed with the doctor's name, qualifications, practice address/es, telephone number and prescriber number (which relates to pharmaceutical benefits). They are only provided to doctors who have a Medicare provider number.
- *Non-personalised (blank) forms* — are distributed as an emergency supply (usually when a doctor has temporarily run out of personalised forms).
- *Locum forms* — have the doctor's name, prescriber number and telephone number (if available) and a space to record the practice where the doctor is working.
- *PBS/RPBS Authority Prescription Forms* — can be in personalised, non-personalised or locum format.
- *Computer PBS prescription forms* — are either continuous or single sheet. On the reverse side they list the name, address and telephone number of the practice, and in the case of a sole doctor practice, the doctor's name.

For dentists:

- *Personalised forms* — have the dentist's name, qualifications, practice address/es, telephone number and prescriber number.
- *Non-personalised (blank) forms* — are distributed for emergency supply only.

For optometrists:

- *Personalised forms* — have the optometrist's name, qualifications, practice address/es, telephone number and prescriber number. These forms can be also be used to prescribe authority-required PBS/RPBS items.

For midwives:

- *Personalised forms* — have the midwife's name, qualifications, practice address/es, telephone number and prescriber number.
- *Non-personalised (blank) forms* — are distributed for emergency supply only.

For nurse practitioners:

- *Personalised forms* — have the nurse practitioner's name, qualifications, practice address/es, telephone number and prescriber number.
- *Non-personalised (blank) forms* — are distributed for emergency supply only.

PBS prescription forms for PBS prescribers are supplied free of charge.

The inclusion of the prescriber number on a PBS prescription enables the pharmacist to be sure the prescription is from a legitimate prescriber and satisfies State/Territory legislation. A PBS prescription written by a dentist, an optometrist, a midwife or a nurse practitioner must include the person's approval number as a PBS prescriber.

PBS prescriptions should be provided to the patient in duplicate, as both parts make up a valid PBS prescription. The patient should be reminded to present both the original and the duplicate copy to the pharmacist.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication. The States of Victoria, Queensland, South Australia and Western Australia, and the Northern Territory have agreed to implement these arrangements.

Ordering forms

Prescribers are asked not to over order. Getting the right amount of forms helps to reduce the cost to taxpayers and helps to reduce paper wastage. Also, the pads may deteriorate if stored over time.

Order forms for standard and authority PBS prescription forms are available from Medicare Australia stationery officers. Contact details are listed in the front of the Schedule. Order forms for computer PBS prescription form stationery are obtained from Medicare Australia (at the address below). Orders should be sent to:

Prescription Pad Order Clerk
Pharmaceutical Branch
Medicare Australia
GPO Box 9826
Sydney NSW 2001
Telephone (02) 9895 3295

Orders for PBS prescription stationery will only be accepted by application in writing and through the channels mentioned above.

Preparing general PBS prescriptions

Do's and Don't's

A PBS prescription is only valid when it is written by a doctor, a dentist, an optometrist, a midwife or a nurse practitioner.

The PBS prescription must be for the treatment of the person named on the PBS prescription. A PBS prescription may only be written for the treatment of one person.

A prescriber cannot write more than one PBS prescription for the same pharmaceutical benefit for the same person on the same day.

Up to **three** pharmaceutical benefit items may be included on a single PBS prescription form except for Authority required, Authority required (STREAMLINED) items and optometrist items. These items must be written on individual forms. Pharmaceutical benefits and non-pharmaceutical benefits should not be listed together on the one PBS prescription form.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication. The States of Victoria, Queensland, South Australia and Western Australia, and the Northern Territory have agreed to implement these arrangements.

If an item has a particular manner of administration it may not, as a pharmaceutical benefit, be administered in any other way, e.g., an ophthalmic preparation may not be prescribed for topical use.

If an item is restricted, and the use for the patient is different from the use specified in the restriction, it cannot be prescribed as a pharmaceutical benefit. The prescriber should write the prescription as a non-PBS private prescription. If a standard PBS prescription form is used for this purpose the 'PBS/RPBS' text must be clearly struck out. It should also be endorsed 'non-PBS'.

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted in the poisons legislation of the particular State or Territory. Legislative requirements in some States/Territories are such that prescribers may be required to prescribe a drug of addiction on a separate PBS prescription. Prescribers must ensure that prescriptions written under the PBS fall within the limits of the prescribing approval granted to the person under State or Territory requirements. It is the prescriber's responsibility to ensure that PBS prescriptions comply with all aspects of his/her prescriber approval. Inclusion of a PBS medicine for prescribing does NOT confer approval for a particular prescriber to prescribe that medicine if it is not authorised to be prescribed in a particular State or Territory

A prescriber cannot prescribe a narcotic drug for him/herself.

Prescribers are issued with individual PBS prescription pads by Medicare Australia for their own use — these pads should not be used by other prescribers, as this can cause confusion through incorrect pharmacy records.

Doctors should, and dentists and optometrists, midwives and nurse practitioners are required to, include their prescriber number on non-personalised PBS prescriptions.

The following admixtures are not pharmaceutical benefits:

- the admixture of two or more ready-prepared items listed in the Schedule; or
- the admixture of a ready-prepared item and one or more extemporaneous drugs listed in Section 4 of the Schedule; or
- the admixture of a non-pharmaceutical benefit item with a pharmaceutical benefit item.

Writing the PBS prescription

The following rules apply for writing PBS prescriptions:

- they must be written in indelible form (i.e., ink or ball-point pen) in the prescriber's own handwriting (exceptions must be approved by Medicare Australia's Chief Executive Officer) either on the standard PBS prescription, or on paper approximately 18 cm x 12 cm,

or they can be generated by computer on a form approved by Medicare Australia. For patient safety reasons, both the original and the duplicate must be legible;

- they must record the prescriber's name and address (and, in the case of dentists, optometrists, midwives and nurse practitioners, the prescriber number), the patient's name, address and entitlement status, and whether the prescription is under the PBS or RPBS;
- they should completely identify the pharmaceutical benefit by detailing the item, dose, form, strength, quantity and instructions for use;
- they should indicate where brand substitution is not permitted. PBS prescriptions must not be prepared using a computer prescribing program that contains a default which would result in all prescriptions being indicated as Brand Substitution Not Permitted;
- where 'solvent required' is included after the form, the volume and number of ampoules must be specified; and
- they must be signed by the prescriber and dated. Forward or back dating is not permitted.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication. The States of Victoria, Queensland, South Australia and Western Australia, and the Northern Territory have agreed to implement these arrangements.

Restrictions

Pharmaceutical benefits listed in the Schedule fall into three broad categories:

Unrestricted benefits - have no restrictions on their therapeutic uses;

Restricted benefits - can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and

Authority required benefits - Authority required benefits fall into two categories:

- *Authority required benefits*are restricted benefits that require prior approval from Medicare Australia or the DVA (noted as **Authority required**)
- *Authority required (STREAMLINED) benefits*are restricted benefits that do not require prior approval from Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as **Authority required(STREAMLINED)**).

Authority PBS prescriptions

Authority required benefits fall into two categories - *Authority required* and *Authority required (STREAMLINED)*.

All PBS prescribers (with the exception of dentists) can write authority PBS prescriptions.

Authority PBS prescriptions cannot have retrospective approval.

Authority required PBS Prescriptions

Approval of authority PBS prescriptions by Medicare Australia may be sought by:

- posting an Authority Prescription Form to Medicare Australia - after approval, Medicare Australia will forward both copies of the prescription to the patient or the prescriber (if it is to be sent direct to the patient, the prescriber should mark the box next to the patient's details);
- calling Medicare Australia Authority Freecall service (1800 888 333); or
- using Medicare Australia PBS authorities website at www.medicareaustralia.gov.au/providers.

Approval of authority prescriptions by the DVA may be obtained either by posting an Authority Prescription Form to the DVA, or by using the DVA Authority Freecall service (1800 552 580).

An authority PBS/RPBS prescription is not valid until it has been approved by Medicare Australia or the DVA. Without this approval, a pharmacist must not supply the item as a PBS/RPBS benefit.

Each Authority required PBS/RPBS item must be written on an Authority PBS/RPBS prescription form, one item per form. Authority PBS prescription forms provide for the following:

- the patient/pharmacist copy, which records prescriber, patient, and pharmaceutical benefit item details. Where required a repeat authorisation, which is used for repeat supply, is attached to the pharmacist/patient copy until the last supply is made. The patient/pharmacist copy is then retained by the pharmacist;
- the Medicare Australia/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Medicare Australia/DVA copy is forwarded to Medicare Australia for processing and payment;
- the prescriber's copy (for computer generated scripts, this is the tear off portion at the base of the script) or Prescriber/Medicare Australia/DVA copy (for handwritten scripts this is the long white copy), is kept by Medicare Australia or the DVA for record purposes when approval is sought in writing. When approval is by telephone or by the authorities website, the prescriber must keep this copy

for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient's age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication. The States of Victoria, Queensland, South Australia and Western Australia, and the Northern Territory have agreed to implement these arrangements.

Authority required (STREAMLINED) PBS Prescriptions

Prior approval is not required from Medicare Australia or DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

This code is listed with the corresponding restriction for each Authority required (STREAMLINED) item and the prescriber must write the code on the authority PBS/RPBS prescription form. An authority prescription for an Authority required (STREAMLINED) item is not valid unless the code is included on the prescription form. Without the streamlined authority code, a pharmacist must not supply the item as a PBS benefit.

There are no Authority Required (STREAMLINED) items in the Repatriation Schedule of Pharmaceutical Benefits.

Authority required (STREAMLINED) PBS prescriptions must be written on an Authority PBS/RPBS Prescription Form, this includes:

- the pharmacist/patient copy, which records prescriber, patient, and pharmaceutical benefit item details. The prescription is given directly to the patient to be dispensed at their pharmacy;
- the Medicare Australia/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Medicare Australia/DVA copy is forwarded to Medicare Australia for processing and payment;
- the prescriber's copy is kept by the prescriber for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient's age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication. The States of Victoria, Queensland, South Australia and Western Australia, and the Northern Territory have agreed to implement these arrangements.

Writing authority PBS prescriptions

The following rules apply:

- only one item may be prescribed per PBS prescription;
- PBS prescriptions must be completed by prescribers in writing, unless otherwise approved by Medicare Australia;
- prescribers should include their name, address, telephone number and **prescriber number** (not provider number);
- prescribers must include the patient's name, address and entitlement status (i.e. whether they are a 'concessional' or 'general patient';
- prescribers must indicate when brand substitution is not permitted. PBS prescriptions must not be prepared using a computer prescribing program that contains a default which would result in all PBS prescriptions being indicated as Brand Substitution Not Permitted;
- in certain circumstances, the prescriber must provide additional information to Medicare Australia with the authority application; and
- the PBS prescription must be signed by the prescriber and dated.

Posted applications which lack necessary information, and therefore cannot be approved, will be returned for correction. If the matter can be clarified via telephone, an Authority to Prescribe Form may be prepared by Medicare Australia or the DVA and sent to the prescriber.

In the case of authority PBS prescriptions approved by telephone, the approval number must be included on the PBS prescription to enable the pharmacist to supply the medication. A prescriber who is granted approval but decides not to continue with the therapy should advise Medicare Australia.

In the case of Authority required (STREAMLINED) prescriptions, the streamlined authority code must be written on the PBS/RPBS prescription form. This enables the pharmacist to supply the medication as a PBS benefit.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication. The States of Victoria, Queensland, South Australia and Western Australia, and the Northern Territory have agreed to implement these arrangements.

Maximum quantities and repeats

The maximum quantity and number of repeats allowed for PBS items are recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). In the case of RPBS items, the recommendations are made by the Repatriation Pharmaceutical Reference Committee (RPRC).

All PBS prescribers (with the exception of dentists) can prescribe repeats.

PBS prescriptions and repeats can be for any quantity up to the maximum. It is not necessary to prescribe the maximum quantity if a lesser quantity is sufficient for the patient's needs. Please clearly indicate the number of tablets, capsules, etc. required and the number of repeats needed, and **do not use** abbreviations such as 'Max. Qty', 'M.Q.', or 'M.R.'.

If a prescriber feels the maximum quantity or number of repeats should be increased for a particular patient, he or she must complete an Authority PBS Prescription Form (see procedures above under 'Authority PBS Prescriptions'). The provision of increased quantities and repeats on authority PBS prescriptions is intended to provide approximately one month's therapy which may be repeated (if clinically appropriate) to provide 6 months' therapy in total. This situation usually arises where higher than normal dosages are required.

Approval for increased quantities and repeats of Authority required, Authority required (STREAMLINED) and Restricted benefit PBS items will be granted only where the reason for the PBS prescription is consistent with the indications published in the Schedule.

Approval for increased quantities and repeats extends only to the provision of a pharmaceutical benefit for the patient and does not imply approval of any aspects of the patient's care, which are the responsibility of the treating prescriber.

Regulation 24

Under this regulation, original and repeat supplies of pharmaceutical benefits can be supplied at the one time if a medical practitioner, a midwife or a nurse practitioner is first satisfied that certain conditions apply, then endorses the PBS prescription 'Regulation 24'. RPBS prescriptions may be endorsed 'hardship conditions apply'.

The medical practitioner, midwife or nurse practitioner must first be satisfied all the following conditions apply:

- the maximum PBS quantity is insufficient for the patient's treatment; **AND**
- the patient has a chronic illness or lives in a remote area where access to PBS supplies is limited; **AND**
- the patient would suffer great hardship trying to get the pharmaceutical benefit on separate occasions.

Regulation 24 does not apply for supply of pharmaceutical benefits on optometrist prescriptions.

Urgent cases

In urgent cases and where State/Territory law allows, a prescriber may telephone a pharmacist and ask that a PBS prescription be supplied. He/she must then forward the written PBS prescription and duplicate to the pharmacist within **seven days of the date of supply**.

This also applies to 'Authority required' authority PBS prescriptions provided prior approval has been given by Medicare Australia or DVA. The follow-up written PBS prescription must include the approval number provided over the phone by Medicare Australia or DVA.

Drugs of addiction

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted and must notify, or receive approval from, the appropriate health authority.

When a PBS/RPBS authority application is for a drug of addiction (other than dexamphetamine sulfate), the following guidelines apply:

- the maximum quantity authorised is generally for one month's therapy (e.g., one week's therapy with three repeats);
- where supply for a longer period is warranted, quantities are usually for up to three months' therapy;
- telephone approvals are limited to one month's therapy.

Prescribers should also state the interval of repeat where repeats are called for, and ensure State/Territory health authorities are notified about ongoing treatment.

Emergency drug supplies

Certain pharmaceutical benefits are provided without charge to prescribers who in turn can supply them free to patients for emergency use.

The Emergency Drug Supply Order Form must be completed in triplicate, signed, and the original and duplicate given to a pharmacist. Each form is valid for the month indicated on the form.

Prescribers may order the maximum quantity of an item provided they do not already have the maximum quantity on hand. The items can only be obtained once a month. Prescribers may also ask for a particular brand of a pharmaceutical benefit. If it is unavailable, they must specify another listed brand, and initial the alteration.

A receipt must be signed by the prescriber, or by an authorised representative, when supplies are received.

Availability of Methoxyflurane for emergency treatment only

A new Emergency Treatment Program (ETP) for medical practitioners has been established to provide for medicines such as Methoxyflurane to be supplied as items for emergency treatment, other than hospital treatment. Unlike other emergency drug supplies, Methoxyflurane, liquid for inhalation 999.9 mg per g, 3 mL (with inhaler) (*Penthrox*®) is not available for prescribing as a general pharmaceutical benefit.

Methoxyflurane is therefore PBS-listed as a 'special pharmaceutical product' under section 100AA, only for emergency treatment, other than hospital treatment. As such, the availability of this drug is provided for under special arrangements under section 100 (1) of the *National Health Act 1953*. The legislative instrument can be viewed on the Federal Register of Legislative instruments at www.frli.gov.au.

For the purposes of administration, Methoxyflurane will be listed with other emergency drug supplies, as outlined above, and be managed by Medicare Australia in the same manner as other emergency drug supply items with the same supply and claiming procedures.

Improving the capacity of the PBS to meet particular Aboriginal and Torres Strait Islander health needs

The PBS includes listings to support the treatment of conditions common in Aboriginal and Torres Strait Islander health settings. These listings are specifically for your patients who identify as Aboriginal and/or Torres Strait Islander persons. Some listings will be medicines recently added to the PBS; others may contain specific restrictions for existing PBS items.

A significant proportion of the higher levels of illness experienced by Aboriginal and Torres Strait Islanders may be addressed through better access to appropriate medicines. The PBS aims to provide greater choice in therapeutic options and to address:

- the greater burden of disease experienced by Aboriginal and Torres Strait Islander peoples; and
- morbidity almost exclusively seen in this population.

How to prescribe these items?

These items are available as "Authority PBS prescriptions". You should obtain approval from Medicare Australia before prescribing these items for patients who identify as Aboriginal and/or Torres Strait Islander persons through the Authority Freecall service [1800 888 333], on line or by mail.

All PBS prescribers except dentists can write Authority PBS prescriptions and your patients will be required to pay their normal PBS co-payment.

Special arrangements apply in remote area Aboriginal Health Services for supplying these PBS items.

Aboriginal and Torres Strait Islander identification

Establishing a client's background may have clinical significance and should be part of routine medical history taking. In the case of Aboriginal and Torres Strait Islander people, this is also relevant to establish eligibility for services such as health checks, specific immunisation programs, and the some PBS items.

Improving the level of identification of Aboriginal and Torres Strait Islander people will also assist in developing initiatives to meet particular needs.

For the purposes of these PBS items a person is Aboriginal and/or Torres Strait Islander if the person identifies himself or herself as being an Aboriginal and/or Torres Strait Islander. Clients should be asked to self-identify either verbally or by completing a form.

- Some people may give this information without being asked.
- It is important not to assume that a person is or is not Aboriginal or Torres Strait Islander.

Asking about Aboriginal and/or Torres Strait Islander identification

Practitioners should ensure that each person attending their practice has the opportunity to identify if they are Aboriginal or Torres Strait Islander. An environment which maintains confidentiality and provides an explanation for this question if requested will assist this process.

- The inquiry may be made verbally and recorded by the general practitioner as part of routine medical history taking at first consultation, or by a receptionist or other staff member. An appropriate question to ask is:
  "Are you (is this child) of Aboriginal or Torres Strait Islander origin?"
- Alternatively, the question may be included on a client self-history or practice record form, using a standard question such as:
  "Are you (is this child) of Aboriginal or Torres Strait Islander origin?"
    - Yes - Aboriginal
    - Yes - Torres Strait Islander
    - Yes - Aboriginal and Torres Strait Islander
    - No

Aboriginal and Torres Strait Islander health

Major causes of excess mortality in Aboriginal and Torres Strait Islander peoples are:

- circulatory conditions (including ischaemic heart disease, hypertension, cerebrovascular disease and rheumatic heart disease);
- external causes (including accident and injury);
- endocrine causes (mainly type two diabetes and its complications); and
- respiratory conditions.

Causes of morbidity vary but include the risk factors and precursors of all of these. They also include infections of the respiratory system, the ears (in particular, chronic suppurative otitis media), the eyes (trachoma in some settings), the skin and the gastrointestinal system. End-stage renal disease is a major cause of hospitalisations, and much early renal disease remains undetected. In some settings, sexually transmissible infections are common.

Living environments affect health and may be compromised by overcrowding, limited access to clean water and sanitation, and poverty. Social and family life may be negatively influenced by an excessive burden of care for family members, by substance use and sometimes by family violence.

Communication and cultural issues

Aboriginal cultures are numerous and diverse in language, customs, non-verbal and verbal communication, geographical locations and experiences. Torres Strait Islanders are a separate people with a distinctly different culture and identity. Aboriginal and Torres Strait Islander people often perceive health differently from other Australians.

For Aboriginal and Torres Strait Islander peoples' health does not just entail the freedom of the individual from sickness but requires support for healthy and interdependent relationships between families, communities, land, sea and spirit. The focus must be on spiritual, cultural, emotional and social well-being as well as physical health

Source: National Aboriginal and Torres Strait Islander Health Council. National Strategic Framework for Aboriginal and Torres Strait Islander Health 2003-2013, Context. Canberra: Commonwealth of Australia; 2004.

To provide effective primary health care to Aboriginal and Torres Strait Islander clients, you need to be aware of the issues surrounding this diversity, and which may have an impact on the delivery of services.

- Aboriginal and Torres Strait Islander people may be reluctant to use mainstream medical services. This may be because of a lack of understanding of the mainstream health system and previous negative experiences within the mainstream health care system.
- Access to adequate health care may be hindered by family obligations (often extended family), lack of transport or money, or geographical isolation.
- English may be the person's second, third or even fourth language. Therefore it may be appropriate to consider the use of an interpreter.
- Aboriginal and Torres Strait Islander people may be reluctant to consult a health care provider of the opposite sex, particularly with regard to women's and men's health issues.

The differences between the cultural and language backgrounds of health service providers and patients, whether urban, rural or remote, may range from minor to extreme.

You should:

- Make efforts to ensure waiting rooms are welcoming to Aboriginal and Torres Strait Islander people, including displaying relevant posters and pamphlets;
- Provide a relaxed setting for the consultation (e.g. sit next to your patient rather than across a desk);
- Allow time at the first consultation to build rapport and trust;
- Ensure the person understands clearly what the service entails and the details of any procedures involved, and possible follow-up or referral requirements;
- Obtain health promotion information appropriate for Aboriginal and Torres Strait Islander patients;
- Allow the patient to have family members present if desired. When inviting family or community members to accompany a patient, ensure the patient fully consents to their attendance and that the community/family members are fully aware of the need for confidentiality;
- Provide gender appropriate staff where possible, for both male and female patients, especially in regard to pap smears, mammograms, sexual health checks, pregnancy checks, antenatal care and postnatal care;
- Encourage all staff in the practice to attend Aboriginal and Torres Strait Islander Cultural Awareness programs, which are widely available;
- Ensure practice staff have awareness of appropriate referral and/or support organisations for Aboriginal and Torres Strait Islander patients; and
- Develop partnerships with local Aboriginal and Torres Strait Islander community organisations.

For more information, pbs-indigenous@health.gov.au

3. Supplying Medicines — What Pharmacists Need to Know

Eligible suppliers

Pharmaceutical benefits are mainly supplied by approved pharmacists – pharmacists who comply with certain conditions. These pharmacists are approved to dispense pharmaceutical benefits from a particular pharmacy.

Other suppliers include approved doctors (usually practising in isolated areas), Friendly Society pharmacies, and approved hospitals. All suppliers are issued with approval numbers by Medicare Australia. They should follow the procedures in these Explanatory Notes.

Unapproved pharmacists *cannot* supply pharmaceutical benefits.

Approval conditions for pharmacists

A pharmacist approved to supply medicines under the PBS:

- can only supply benefits from the pharmacy that he/she is operating;
- will not supply to anyone any pharmaceutical benefit that attracts a Commonwealth contribution for free, or for a price that is less than the relevant patient contribution;
- will clearly advertise that any offer for free or cut-price medicines does not include pharmaceutical benefits which have a Commonwealth contribution;
- will not pay rebates or refunds of patient contributions;
- will publicly display a notice setting out the pharmacy's normal trading hours;
- is obliged to supply pharmaceutical benefits at the pharmacy at any hour if a PBS prescription is marked 'urgent' and initialled by the prescriber;
- will keep adequate stocks for the supply of pharmaceutical benefits;
- may be called on by Medicare Australia to provide details of stocks of pharmaceutical benefits or preparations for pharmaceutical benefits; and
- must keep the duplicates of all old format PBS prescriptions, and the patient/pharmacist copies of all new format PBS prescriptions, with a Commonwealth contribution for at least one year from the date of supply. This includes PBS prescriptions ordering repeats when it is the final supply, and order forms for emergency drug supplies. Please note that some State/Territory laws require these copies to be kept for longer periods.

Before supplying pharmaceutical benefits

Several steps must be taken before a pharmaceutical benefit is supplied.

Firstly, a pharmacist must endorse the PBS prescription and duplicate with his/her name and approved supplier number.

Secondly, a PBS prescription identifying number must be given to the PBS prescription item on both the PBS prescription and duplicate. Any recognised series of numbers may be used.

If more than one item is on a PBS prescription, a separate identifying number should be allocated to each item.

In the case of a repeat authorisation, the same PBS prescription identifying number(s) must be carried through for each item. A pharmacist must also allocate his/her own identifying number on the repeat authorisation. It must be written alongside the date and place of supply.

Supplying pharmaceutical benefits

Do's and Don'ts

Except in urgent cases (see details under '2. Prescribing Medicines ... Urgent cases'), pharmacists are authorised to supply pharmaceutical benefits only after they receive:

- the pharmacist/patient and Medicare Australia or DVA copies of a valid PBS prescription which is not more than 12 months old; or
- the pharmacist/patient and Medicare Australia or DVA copies of an approved authority PBS prescription or an authority to prescribe which is not more than 12 months old; or
- a repeat authorisation attached to a patient/pharmacist PBS prescription not more than 12 months after the date of the original PBS prescription.

A pharmacist must not supply an Authority required (STREAMLINED) item unless the prescriber has written the four digit streamlined authority code on an authority PBS/RPBS prescription.

A pharmaceutical benefit cannot be supplied more times than specified in the PBS prescription.

A pharmacist cannot add to, delete from, or alter a PBS prescription in any other way. However, there may be circumstances where after contacting a prescriber, the pharmacist can clarify the prescriber's intentions and endorse the PBS prescription accordingly.

Once a pharmaceutical benefit has been supplied to a patient, it may not be supplied to that patient again:

- on the same day or within the next 20 days, if it is a benefit (other than an eye preparation) that has five or more repeats allowed in the Schedule; or
- on the same day or within the next four days (e.g., if a pharmaceutical benefit is supplied on a Monday, it cannot be supplied again to that patient until the next Saturday) in the case of other benefits.

Exceptions to this are:

- when a PBS prescription is endorsed with the words 'Regulation 24' or 'hardship conditions apply' (see below under 'Regulation 24'); and
- If a pharmacist believes a repeat supply is needed without delay for the treatment of the person, or a previous supply has been destroyed, lost or stolen. In this case, the pharmacist can provide another supply but must write ‘immediate supply necessary’ and sign the PBS prescription.

A pharmacist can supply an alternative pharmaceutical benefit without reference to the prescriber, provided that:

- the PBS prescription does not indicate that only the pharmaceutical benefit prescribed is to be supplied (ie substitution is not permitted); and
- the Schedule states that the prescribed benefit and the substitute benefits are equivalent; and
- supply of the substitute benefit does not contravene relevant State/Territory law; and
- the substitute benefit is a listed brand in the Schedule.

Pharmacists must heed State/Territory laws when supplying drugs listed as narcotic, specified or restricted in legislation of the particular State or Territory.

What to do if the Schedule changes

If an item or brand is deleted from the Schedule, it *cannot* be supplied as a pharmaceutical benefit from the date the deletion takes effect – regardless of whether the PBS prescription was written before this date. This includes repeat authorisations. (Special conditions applying to RPBS prescriptions are detailed in the RPBS Explanatory Notes.)

However, if restrictions on the prescribing of a pharmaceutical benefit change, or the maximum quantity or number of repeats is altered in the Schedule, valid PBS prescriptions written before the date of effect of the change *may* still be supplied as pharmaceutical benefits, under the conditions applying at the date of prescribing.

Suspected forgery

Pharmacists should take all reasonable steps to satisfy themselves that all items on a PBS prescription were written by a medical practitioner, a dentist, an optometrist, a midwife or a nurse practitioner.

Regulation 24

This regulation allows pharmacists to supply a pharmaceutical benefit and all of its repeats at the one time.

The PBS prescription must be endorsed by the medical practitioner, midwife or nurse practitioner with the words 'Regulation 24' if it is an item under the PBS, or 'hardship conditions apply' if it is being supplied under the RPBS. (For more information see under `2. Prescribing Medicines ... Regulation 24'). Regulation 24 does not apply for supply of pharmaceutical benefits on optometrist prescriptions.

Repeat authorisations

When a PBS prescription calls for repeat supplies, the pharmacist shall prepare a Repeat Authorisation Form, except when the PBS prescription is marked `Regulation 24'.

The repeat may be requested on a standard PBS prescription, an authority PBS prescription or an Authority to Prescribe Form, or on an earlier repeat authorisation. In the latter case, it must come with the duplicate PBS prescription, or in the new format, the "patient/pharmacist copy".

Preparing Repeat Authorisation Forms

A Repeat Authorisation Form must show:

- the category of benefit (concession or general) – by placing a cross (x) in the relevant box;
- the patient's name and full address;
- in the case of repeats authorised on authority PBS prescriptions, the authority prescription number;
- details of the original PBS prescription stating the item, form, strength, quantity and directions;
- if substitution has occurred, the name of the brand actually supplied;

- for the first supply, the pharmacy name, address and approval number, the date of the original PBS prescription and the allotted PBS prescription identifying number;
- for subsequent supplies, the pharmacy approval number, and the date and PBS prescription number of the original prescription;
- the number of times the item is to be repeated and the number of times it has been supplied;
- the name and pharmacy approval number of the pharmacist issuing the repeat authorisation; and
- the date of supply.

When a repeat authorisation is prepared for any further repeats or deferred supply, a pharmacist must attach the duplicate copy of an old format PBS prescription, or the patient/pharmacist copy of a new format PBS prescription, and give both to the patient at the time of supply.

Repeat authorisations for injectables and solvents

Where an injectable pharmaceutical benefit requires a solvent, both items should be treated as one pharmaceutical benefit. If repeats are needed, only one repeat authorisation is to be prepared. Details of the injectable and the solvent should appear in the space provided for the 'original prescription transcription'.

Repeat authorisations for deferred supply

When a PBS prescription orders a number of pharmaceutical benefit items, but the patient does not need all of the items at the same time, a separate repeat authorisation for each deferred item must be prepared. The words 'original supply deferred' should be indicated across the relevant item on the original PBS prescription, its duplicate, and on the repeat authorisation.

Deferred items must not be claimed on the original PBS prescription.

The Repeat Authorisation Form when it is used for a deferred supply, is issued in the same way as normal repeat authorisations except that:

- '0' is to be inserted in the space for 'no. of times already dispensed'; and
- if no repeats are ordered, '0' is to be inserted in the space for 'no. of repeats authorised'.

Supplying a benefit on a deferred supply repeat authorisation is to be treated as if it is the first time of supply. If repeats are directed, the normal procedure for repeat authorisations applies. Details of the pharmacy at which the deferred supply was authorised are to be written onto subsequent repeat authorisations.

Authority PBS prescriptions

If a pharmacist is presented with an authority PBS prescription and is not sure if it has been approved, he or she should contact Medicare Australia. Please note that Medicare Australia will not provide clinical information.

If the authority PBS/RPBS prescription is for an Authority required (STREAMLINED) item the pharmacist should ensure that the prescriber has written the four digit streamlined authority code on the prescription, this enables the pharmacist to supply the item as a PBS benefit.

Urgent cases

In urgent cases and where State/Territory law allows, pharmacists can supply a pharmaceutical benefit to a person without a PBS prescription, provided details of the prescription are given by the prescriber via telephone or other means. The prescriber must then forward the written PBS prescription and duplicate to the pharmacist within **seven days of the date of supply**.

Where a pharmaceutical benefit needs prior approval from Medicare Australia or the DVA, the prescriber must obtain approval and then advise the pharmacist of the PBS prescription and approval details. Only an original supply can be provided in this manner, not repeats.

Receipts

A person receiving a pharmaceutical benefit item must sign and date a receipt for it. If the person is not the patient, that person must also endorse the PBS prescription or repeat authorisation with his/her address. A receipt cannot be obtained until supply of the benefit has been made.

If a pharmaceutical benefit has to be sent through the post, by rail, or by other means, and a receipt is not practical, the pharmacist must certify on the PBS prescription or repeat authorisation that the benefit has been supplied, and write the date of supply and details of how it was sent. For example, if a pharmaceutical benefit is mailed to a patient on 1 April 2008, the pharmacist should write: "Certified supplied – mailed to patient 1 April 2008 (name of pharmacist) (signature of pharmacist) (date of certification)".

If an item is supplied in an urgent case, or to a person who cannot read or write, the pharmacist should sign and date a statement on the PBS prescription or repeat authorisation, stating the item has been supplied and the date on which it was supplied, and explaining why there is no receipt. For example, if a pharmaceutical benefit is supplied to a patient with a broken arm on 1 May 2008, the pharmacist should write: "Certified supplied 1 May 2008 – patient has a broken arm and is unable to sign (name of pharmacist) (signature of pharmacist) (date of certification)".

Only the pharmacist approved to supply pharmaceutical benefits can certify supply.

Emergency drug supplies

Pharmacists may supply certain pharmaceutical benefit items free of charge to medical practitioners or other authorised prescribers for emergencies if they receive an Emergency Drug Supply Order Form in duplicate, signed by the medical practitioners or other authorised prescriber.

Pharmacists must be satisfied the form was completed by a medical practitioner or other authorised prescribers and includes the medical practitioner's or other authorised prescriber's name and address. If a pharmacist does not know the medical practitioner or other authorised prescriber, he/she should confirm the medical practitioner's or other authorised prescriber's registration and endorse this on the back of the form.

For more information about emergency supplies see under 2. Prescribing Medicines ... Emergency drug supplies'.

4. Patient Charges

Type of patient

There are two types of PBS beneficiaries, general patients, who hold a Medicare card and concessional patients who hold a Medicare card and one of the following:

- Pensioner Concession Card
- Commonwealth Seniors Health Card
- Health Care Card
- Repatriation Health Card for All Conditions (gold) — concessional patients under RPBS
- Repatriation Health Card for Specific Conditions (white) — only regarded as concessional patients for RPBS prescriptions unless they hold a separate entitlement from Centrelink, otherwise they are general patients
- Repatriation Pharmaceutical Benefits Card (orange) — concessional patients under RPBS
- Safety Net Concession Card or Safety Net Entitlement Card — issued by Medicare Australia.

Concessional patients are recognised by public hospitals in all States and Territories apart from South Australia (where DVA beneficiaries are treated as general patients) and New South Wales (where holders of a white DVA card are treated as general patients).

Under the Reciprocal Health Care Agreements, visitors from participating countries (see the introduction of this section for the list of countries) are treated as general patients and do not have concessional entitlements. To receive pharmaceutical benefits these visitors may need to present a temporary Medicare card or their passport. Pharmacists should contact Medicare Australia if they have enquiries about these arrangements.

Establishing entitlement

PBS prescription forms supplied by Medicare Australia have spaces provided for details of a patient's entitlement status. Anyone can enter this information, which must include:

- a cross (x) in the appropriate box to indicate the level of patient contribution;
- the complete Medicare number (including individual reference number) or complete Veteran file number on the card; and
- if applicable, the complete concession number on the card.

The person who signs the receipt for pharmaceutical benefits also accepts responsibility for the validity of the entitlement information on the PBS prescription.

All PBS prescriptions must have a Medicare or Veteran file number. All concessional PBS prescriptions must have a concession number. However, it is not necessary for the Medicare (Veteran file) or the concession number to be endorsed on the PBS prescription if it is included in the electronic prescription details supplied by a pharmacist who is using the Claims Transmission System.

What to charge

Patient contribution

Under the PBS, the maximum cost for a pharmaceutical benefit item at a pharmacy is $35.40 for general patients and $5.80 for concessional patients, plus any applicable special patient contribution, brand premium or therapeutic group premium. General patients who have reached the safety net threshold (see details under '5. The Safety Net Scheme') may receive pharmaceutical benefits at the concessional rate, plus any applicable special patient contribution, brand premium or therapeutic group premium.

Patients who have a Safety Net Entitlement Card (see details under '5. The Safety Net Scheme') may receive PBS items free of charge, except for any applicable special patient contribution, brand premium or therapeutic group premium.

The contribution rate for general patients as outpatients at public hospitals in most of Australia is $28.30. The exceptions are in Queensland and in hospitals participating in the pharmaceutical reforms where they pay the safety net value of an item listed in the Schedule (see details

under '5. The Safety Net Scheme'), or up to the general co-payment amount for items not listed in the Schedule. The public hospital pharmaceutical reforms enable participating public hospitals to prescribe and supply pharmaceutical medication from the PBS to outpatients and patients upon discharge. A range of chemotherapy drugs is also available for day-admitted and non-admitted chemotherapy patients.

The contribution rate for concessional patients in all public hospitals is equal to the concessional co-payment amount.

The supply of a pharmaceutical benefit or a Repatriation pharmaceutical benefit to a patient is GST-free. Goods and services tax must not be included in the price charged to a patient for the supply of a PBS or RPBS script.

It is the patient's responsibility to pay any charge lawfully imposed by an approved pharmacist or supply may be refused.

The patient contribution rates are adjusted on 1 January each year in line with inflation.

Patient contributions for early supply of some PBS medicines

Prescriptions for some PBS and RPBS pharmaceutical benefits are not eligible for safety net benefits if re-supplied within 20 days of a supply of the same pharmaceutical benefit for the same person. This is known as the 'Safety Net 20 day rule' and came into effect on 1 January 2006.

Where a prescription is subject to the Safety Net 20 day rules:

- the patient contribution does not count towards the Safety Net, and
- after the Safety Net threshold is reached, the usual patient co-payment amount for the corresponding entitlement level (not the Safety Net amount) applies.

For example: The payment for such a prescription for a patient with a Safety Net Entitlement Card would be the concessional co-payment amount — not free. For a general patient with a Safety Net Concession Card, the usual general co-payment amount would apply — not the concessional amount.

The Safety Net 20 day rule does not apply to PBS/RPBS prescriptions originating from hospitals or day hospital facilities.

Special patient contributions, brand premiums and therapeutic group premiums

A special patient contribution is payable for a pharmaceutical benefit when a supplier will not supply it at the benchmark price. Any extra charge for a higher priced benefit is paid by the patient, together with their usual patient contribution. Other than for bleomycin sulfate (available under the 'Efficient Funding of Chemotherapy - Section 100 Arrangements'), exemptions on medical grounds are available, but must be granted by Medicare Australia. For RPBS special patient contribution arrangements see the RPBS Explanatory Notes.

Under the brand premium arrangements, reimbursement to pharmacists is based on the lowest-priced brand. Any extra charge for a higher priced brand is paid by the patient, together with their usual patient contribution.

Under the therapeutic group premium arrangements, reimbursement to pharmacists is based on the lowest priced benefit items within identified therapeutic groups. Any extra charge for a higher priced benefit is paid by the patient, together with their usual patient contribution. Exemptions on medical grounds are available, but must be granted by Medicare Australia.

Special patient contributions, brand premiums and therapeutic group premiums apply to maximum quantities. When a quantity is less than, or — on an authority or 'Regulation 24' PBS prescription — more than, the maximum, the contributions or premiums will be a factor of the maximum quantity, using standard pricing rules.

There are separate arrangements for PBS prescriptions in certain public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia and the Northern Territory have these arrangements.

Solvents

Where a solvent is prescribed as a part of a pharmaceutical benefit, only one patient contribution is charged.

Increased quantities

Where a prescriber has written an authority PBS prescription for a quantity greater than the maximum, the patient contribution should be made for each supply of the increased maximum quantity.

Regulation 24

For 'Regulation 24' PBS prescriptions, a pharmacist should charge the usual patient contribution for the original and for each repeat quantity needed to make up the total supply (plus any applicable special patient contribution, brand premium or therapeutic group premium, for the original and each repeat quantity in the total supply).

After hours

A pharmacist may charge an extra fee if supplying a PBS item outside normal trading hours. This charge is paid by the patient and does not count towards the safety net.

Delivery

A charge can be added for delivering pharmaceutical benefits from the pharmacy. This charge does not count towards the safety net. For RPBS delivery arrangements refer to the RPBS Explanatory Notes.

5. The Safety Net Scheme

The PBS safety net protects patients and their families requiring a large number of PBS or RPBS items. For the purposes of the scheme, the family includes the person:

- the partner or de facto partner;
- children under the age of 16 who are in the care and control of the person; or
- dependent full-time students under the age of 25.

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on prescription record forms. When a patient reaches the Safety Net threshold within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the rest of that year. Any applicable special patient contributions, brand premiums or therapeutic group premiums must still be met by the patient.

The safety net threshold is reached by accumulating eligible patient contributions for PBS prescriptions supplied through community pharmacies and private hospitals and for out-patient medication supplied by public hospitals.

Pharmaceutical benefits (including authority items) can only be counted towards the safety net threshold when prescribed and supplied according to PBS conditions. A medicine supplied by a pharmacist not approved to supply pharmaceutical benefits cannot count towards the safety net.

Prescriptions for some pharmaceutical benefits are not eligible for safety net arrangements if re-supplied within 20 days of supply of the same item for the same person and the patient contribution cannot count towards the safety net (see also details under '4. Patient Charges' and '7. How Pharmacists Claim Reimbursement'). This does not apply to out-patient medications in public hospitals or to any prescriptions originating from a hospital or day hospital facility.

There are separate arrangements for PBS prescriptions in certain public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia and the Northern Territory have these arrangements.

Safety net thresholds

There are two safety net thresholds. The general patient safety net threshold is currently $1363.30. When a person and/or their family's total applicable co-payments reach this amount, they may apply for a safety net concession card and pay the concessional co-payment amount of $5.80 plus any applicable premium for pharmaceutical benefits for the rest of that calendar year.

The concessional safety net threshold is $348.00 (this also applies to gold, white or orange card holders under the RPBS). When a patient and/or their family's total applicable co-payments reach this amount, they may apply for a safety net entitlement card and may receive pharmaceutical benefits free of charge (except for any applicable premium) for the rest of that calendar year.

Brand premiums, therapeutic group premiums and special patient contributions do not count towards the safety net thresholds.

The safety net thresholds are adjusted on 1 January each year in line with inflation.

Safety net cross-over arrangements

Some patients and/or members of their families will change between general patient and concessional patient status during a calendar year. Patients should apply for the safety net card appropriate to their status at the time they apply.

Concessional patients who were previously general patients can apply for a safety net entitlement card when they reach the concessional safety net threshold. In this case, any pharmaceutical benefits previously supplied at the general co-payment rate in that calendar year will be counted at the concessional rate per item.

General patients who were previously concessional patients can apply for a safety net concession card when they reach the general safety net threshold. In this case, any pharmaceutical benefits previously supplied at the concessional rate in that calendar year will be counted at the concessional rate per item.

In the case of families where one parent holds a concession card and other family members are general patients, the family can choose to apply for either a safety net entitlement card or a safety net concession card.

To receive a safety net entitlement card, all pharmaceutical benefits (including general pharmaceutical benefits) are counted at the concessional rate per item until the concessional threshold is reached. To receive a safety net concession card, general pharmaceutical benefits are counted at the general co-payment rate per item and concessional pharmaceutical benefits at the concessional rate per item, until the general safety net threshold is reached.

White DVA card holders may either be general or concessional patients (depending on their Centrelink entitlements). If they are receiving treatment for a specific disability accepted by the DVA, they are also supplied with specified items under the RPBS at the concessional rate per

item. Therefore, these patients are encouraged to maintain a concessional prescription record form, plus a general prescription record form for items not covered under the RPBS.

White card holders may choose at any time to count contributions made at the general level towards the concessional safety net threshold and receive credits equal to the concessional co-payment amount for each pharmaceutical benefit purchased. Alternatively, white card holders can count contributions at the concessional level towards the general safety net, and receive credits equal to the concessional co-payment amount for each pharmaceutical benefit purchased.

Gold or orange DVA card holders may receive all of their prescription items under the RPBS, and only pay the concessional co-payment amount for each item.

Dependants of white, gold or orange card holders are treated separately and may be either general patients or concessional patients. Their prescriptions may be included in the cross-over arrangements.

Recording PBS prescriptions

There are two types of prescription record forms to record PBS prescription items. A blue form, used for items obtained at community pharmacies and available from community pharmacies, Medicare offices and Medicare Australia; and a grey form, used by out-patients who pay for items at public hospital pharmacies and available from hospital out-patient departments or Medicare Australia.

Patients should record their general or concessional status on the prescription record form, enter their Centrelink, DVA and/or Safety Net Concession/Entitlement Card number, and list family members covered. General patients must also record their Medicare number when applying for a safety net concession card.

Details to be entered on the form by the pharmacist are:

- date of supply;
- PBS/RPBS code number of the item (for community pharmacies only);
- the safety net value of the item (for community pharmacies only);
- pharmacist's approval number (for community pharmacies only);
- item identification — medicine code, name of medicine or abbreviation (for public hospitals only);
- hospital charge (for public hospitals only);
- hospital safety net number (for public hospitals only); and
- signature of the authorised person making the entry.

Community pharmacists should record in the 'safety net value' column:

- the patient contribution when it is less than the PBS dispensed price; or
- the safety net value shown in the Schedule, or any lesser amount charged, if the PBS dispensed price is less than or equal to the patient contribution. The pharmacist may discount the price for these items.

Some computer software suppliers provide a special label to record this information on the prescription record forms. Some suppliers also provide a computer printout as a prescription record form.

The patient is responsible for maintenance and storage of their prescription record form. However, it may be kept in the pharmacy. A person (or family) may have more than one prescription record form.

Hospital prescription record forms

Items to be recorded on hospital prescription record forms must be approved by the hospital's pharmaceutical advisory committee and may be listed on a hospital's formulary (a list of pharmaceutical items approved by the committee for the treatment of particular illnesses), or authorised on a patient-by-patient basis.

Multi-item prescription forms

If a patient submits a multi-item PBS prescription form, which would take the total co-payments past the safety net threshold, any items in excess are treated as entitled items once a safety net entitlement/concession card is issued.

Excess items should be treated as 'deferred supply' items.

For example, if a family has a new PBS prescription for three items and the first takes the family up to the threshold, then this item should be supplied at the general rate. If the second item takes the family over the threshold, the pharmacist should then issue a safety net concession card and supply both this and the third item at the concessional rate. This involves the deferral of two items, recording the safety net concession card number, and the subsequent supply of these items.

Qualifying PBS prescriptions

A PBS prescription should be supplied at the concessional rate or free of charge plus any applicable premium, when the safety net value or hospital charge for that PBS prescription takes the total co-payments over the qualifying amount for a safety net entitlement/concession card.

Lost prescription record forms

If a prescription record form has been lost, stolen or destroyed, a pharmacist may prepare a duplicate copy, but is under no obligation to do so.

Retrospective entitlement and patient refunds

Responsibility for claiming entitlements rests with the patient. If items recorded on a prescription record form have exceeded the safety net threshold, the cost of those items in excess of the limit cannot be refunded by a pharmacist.

However, if the patient failed to apply for a safety net entitlement/concession card on reaching the safety net threshold they should write to Medicare Australia and provide copies of pharmacy accounts or a signed statement from the pharmacist giving the date of supply, description and cost of items supplied and paid for. A copy of the relevant prescription record form should also be provided. If these are not available, the patient should give the name of the pharmacy where the card was issued and the number on the card so that Medicare Australia can locate the prescription record form in its records. Cash refunds are not available. Medicare Australia contact details are provided in the 'Addresses — Medicare Australia' part of the Schedule.

If the patient cannot satisfy a pharmacist that they have a current entitlement and is charged the general patient price, the pharmacist should issue the patient with a receipt and a claim form (provided by Medicare Australia). The patient can then obtain a refund via Medicare offices or PBS processing centres. RPBS prescription refunds are paid at DVA State offices.

Medicare Australia can only pay refunds for PBS items supplied through approved pharmacies. Refunds for hospital supplied items should be referred to the relevant hospital or health department. Refunds cannot be made where the patient was charged the general or concessional amount instead of the safety net concessional or safety net entitlement amount as a result of the safety net 20 day rule. Receipts for prescriptions where the safety net 20 day rule has applied must include 'SN20DR' to indicate the reason for the amount charged.

There are separate arrangements for PBS prescriptions in some public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia and the Northern Territory have these arrangements.

Applying for a Safety Net Entitlement/Concession Card

Once the safety net threshold has been reached, the person covered by a prescription record form may complete the application and declaration to get a safety net entitlement/concession card. Please note that software packages that produce computer generated applications must be approved by Medicare Australia.

If the card is issued to a dependent child or student, it should be in the name of a parent.

When issuing entitlement/concession cards, pharmacists do not have to check all prescription record form details. However, they should ensure each entry has been signed and that the prescription record form total qualifies the patient for the relevant safety net card.

When appropriate the pharmacist should check that the patient's Medicare card number is on the prescription record form.

Issuing a Safety Net Entitlement/Concession Card

When satisfied that the individual or family is entitled, the pharmacist should issue the next blank safety net entitlement/concession card with the following details:

- the names of family members covered. If there are more than eight family members, a second card should be issued listing the card holder and family members not listed on the first card. The prescription record form has space to record that two cards have been issued, and
- the two-character code to indicate the relationship to the card holder. Applicable codes are:
    - SP - partner;
    - DC - child under 16 years; and
    - DS - dependent full-time student under 25 years.

The pharmacist should be satisfied that only family members are listed on the card. The unused space on the card should be ruled through to prevent extra names being added. The sticky label from the safety net entitlement/concession card, pre-printed with the card number, should be attached to the prescription record form. The pharmacist should sign and stamp each prescription record form with the pharmacy stamp and enter the card issue details on a safety net — claim for payment form.

Issuing supplementary cards

A pharmacist may give a card holder a supplementary card for a partner or dependant only at the time the original card is issued. The duplicate card should be recorded in the additional box on the prescription record form.

Later requests for supplementary cards and requests to add a new family member to the original card are to be referred to Medicare Australia.

Notification to Medicare Australia and claim for payment

Payment for issuing a safety net entitlement/concession card is made after the safety net — claim for payment form is sent to Medicare Australia, no later than one month after a card is issued.

Each form must be accompanied by all supporting documentation (prescription record form and cancelled or void safety net entitlement/concession cards).

Payment will not be made for void cards.

Lost Safety Net Entitlement/Concession Cards

When a card has been lost, damaged, stolen or destroyed, a pharmacist cannot re-issue a person with a replacement card. The original card holder (or partner) must apply to Medicare Australia.

Pharmacy record of issued cards

A record of all cards issued must be kept at the pharmacy from which the pharmacist is approved to supply pharmaceutical benefits. The duplicate ('bookfast') copy in the safety net — claim for payment book is provided for this purpose.

6. Medicare Australia Entitlement Checks

General Patients

Medicare Australia validates a patient's entitlement to pharmaceutical benefits by checking Medicare and/or Veteran file numbers in pharmacist's claims. If a number is not recorded correctly, a patient cannot be identified against Medicare Australia's Pharmaceutical Benefits Entitlement File and entitlement cannot be established.

If the Medicare or Veteran file number provided in the pharmacists' claims is incorrect or the number and the name supplied do not match Medicare Australia records to enable patient identification, an appropriate warning or rejection code will be returned to the pharmacy. These notifications of missing or incorrect Medicare or Veteran file numbers are provided to pharmacists in their reconciliation statement produced after the claim period has been paid by Medicare Australia.

Special numbers are available for use in certain circumstances for eligible people who are unable to provide a Medicare number.

Concessional Patients

Medicare Australia routinely validates a patient's entitlement to free or concessional benefits by checking concessional numbers in pharmacists' claims. If a number is not recorded correctly, a patient cannot be identified against Medicare Australia's Pharmaceutical Benefits Entitlement File and entitlement cannot be established.

When a number is found to be from a card which was incorrect, expired at the time of supply or entitlement was withdrawn, warning or rejection codes will be returned to the pharmacy to assist with validation of concessional entitlement in relation to future claims from the same patient.

Entitlement checking procedures

General Patients

Once a pharmacist has been notified by Medicare Australia of an incorrect Medicare or Veteran file number he/she should correct the number for future claims by:

- updating his/her system to reflect the correct number provided by Medicare Australia (if patient consent to do so has been obtained); or
- speaking to the patient; or
- obtaining patient consent and calling Medicare Australia on the Improved Monitoring of Entitlements (IME) (132 290 — select option 1).

If the patient presents a Medicare card that appears correct, but according to Medicare Australia is not a valid number, or not a valid number for that person, a pharmacist may use a special number. A photocopy of the card, or a form must accompany the use of this number. The form is available on Medicare Australia's website or by calling 132 290.

Concessional Patients

Once a pharmacist has been notified by Medicare Australia of an incorrect concessional entitlement number, he/she should view the entitlement card to confirm the entitlement number, and start and end dates, when the patient next presents a PBS prescription.

Step by step

Pharmacists should take the following steps where concession entitlement does not appear to be valid or current:

- Re-confirm entitlement with the cardholder/customer;

- Contact Medicare Australia on 132 290, with consent, to confirm the cardholder/customer concession status;
- If Medicare Australia advises that the cardholder/customer is concessionally entitled to receive the PBS medicines on that day, supply the prescription as a concessional entitlement;
- If Medicare Australia advises that the cardholder/customer is not concessionally entitled to receive the PBS medicines on that day, supply as a general prescription. Provide the customer with the information sheet "Your entitlement card" which explains entitlement checking to the customer and the steps they can follow if they are concessionally entitled.

7. How Pharmacists Claim Reimbursement: Information Required

Medicare Australia uses a computerised system for pricing PBS prescriptions, repeat authorisations and emergency drug supply orders, and for calculating claims.

The payment system is designed to pay pharmacists correctly for the pharmaceutical benefits they supply. It is essential instructions are followed carefully and that each document includes all relevant information. Accurate and complete data ensures claim ayment is not delayed.

PBS Prescription identification

Pharmacists must include certain information on each PBS prescription sent in for claim, as specified below. It is important that this information is entered correctly and in the right place on the PBS prescription. This information will be included in a sticker produced by pharmacy software.

The sticker should be placed on the extreme left front of a PBS prescription, opposite each item being claimed. It must not obscure any details written by the prescriber. Most prescribers use PBS prescriptions, which have space for the sticker. If a sticker is not used, a PBS prescription identification stamp can be used or the information can be written in the same place, and in the same order.

Pharmacists should avoid writing over, or placing the sticker over, the prescriber number pre-printed on PBS/RPBS prescriptions, or the prescriber number box on PBS dental and optometrist, midwife and nurse practitioner prescriptions.

The sticker is not necessary for current repeat authorisation, emergency drug supplies, or for old style authority PBS prescription and authority to prescribe forms, as they have printed spaces for the necessary details. However, it is required for the new format authority PBS prescription forms.

The following information should be entered next to the appropriate letter on the sticker or stamp:

- 'S' — the serial number for the claim
- 'A' —
    a. the price claimed for pricing elected PBS prescriptions, exceptional PBS prescriptions and RPBS non-scheduled prescriptions (see under 'Extemporaneously-prepared pharmaceutical benefits not listed in the Standard Formulae List' for explanations of pricing elected PBS prescriptions and exceptional PBS prescriptions); and/or
    b. confirmation that the PBS prescription is endorsed 'Regulation 24' or the RPBS prescription is endorsed 'hardship conditions apply'; and/or
    c. a claim for a glass dropper bottle where applicable; and/or
    d. any clarification of the prescription which will assist Medicare Australia payment processing.
- 'No.'— the PBS prescription identifying number.

Serial numbers

PBS prescription, repeat authorisation, authority PBS prescription, and emergency drug supplies forms submitted in each claim must bear consecutive serial numbers starting with:

- 1 – for emergency drug supplies;
- 1 – for general benefits;
- C1 – for concessional and Safety Net Concession Card benefits;
- E1 – for Safety Net Entitlement Card benefits; and
- R1 – for RPBS benefits.

Each serial number should also be noted on any document kept by the pharmacist for record purposes.

Each emergency drug supply item should be given a serial number, e.g., if there are five items on the first form in the claim, the first item on the second form in the claim will start ith the serial number 6.

For prescriptions subject to the Safety Net 20 day rule, the serial number corresponds to the resulting payment category for the pharmaceutical benefit as supplied, not the patient's entitlement category.

Repeat authorisations for authority PBS prescriptions

When a benefit is supplied on a repeat authorisation which needed an authority PBS prescription, the serial number must be prefixed with the letter 'A' for a general benefit; 'AC' for a concessional benefit or a benefit supplied to a Safety Net Concession Card holder; 'AE' for a Safety Net Entitlement Card holder; or 'AR' for a RPBS benefit.

Repeat authorisations for deferred supply

When a benefit is supplied on a repeat authorisation prepared for deferred supply, the serial number must be prefixed with the letter 'D' for a general benefit; 'DC' for a concessional benefit or a benefit supplied to a Safety Net Concession Card holder; 'DE' for a Safety Net Entitlement Card holder; or 'DR' for a RPBS benefit.

Injectable item ordered with a solvent

When both an injectable item and a solvent are to be supplied, only one serial number is used. This number should be placed on the left hand side of the prescription, opposite the injectable item.

Dropper containers

Dispensed prices for extemporaneously-prepared eye drops, ear drops and nasal instillations include the price of a polythene dropper container. However, if a glass dropper container is supplied, payment should be claimed by writing 'glass bottle' in box 'A' of the stamp.

Extemporaneously-prepared pharmaceutical benefits not listed in the Standard Formulae List

When a formula is not listed on the Standard Formulae List, the PBS prescription is paid at an average of 10 g/mL rate for the type of preparation, unless the pharmacist elects otherwise. A pharmacist may price an exceptional PBS prescription, or elect to price all non-pre-priced extemporaneous PBS prescriptions.

PBS prescriptions paid on an average price basis

If the PBS prescription is to be claimed as an exceptional PBS prescription, the pharmacist should write details of the formula supplied on the PBS prescription or repeat authorisation form; price the PBS prescription in accordance with the pricing principles (as detailed in '9. Pricing PBS Prescriptions'); and enter the calculated price on the sticker.

An exceptional PBS prescription is for an extemporaneously-prepared pharmaceutical benefit that is not included in the Standard Formulae List and for which the price of the ingredients (based on basic pricing rules) is twice or more than the recovery price of the ingredients calculated on an average price basis. Further information on pricing PBS prescriptions can be accessed from the book let titled *Explanation of Current Pricing*on the Medicare Australia's website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

Pricing non-pre-priced extemporaneous preparations

Pharmacists should notify Medicare Australia when they elect to price non-pre-priced extemporaneous preparations. Each PBS prescription should be priced in accordance with the pricing principles and that price entered on the sticker.

RPBS prescriptions for items not included in either the PBS or RPBS Schedule

When a prescription for a RPBS patient is for an item not included in either the PBS or the RPBS Schedule, the price claimed should be entered on the sticker. Full details on pricing and availability of such items under the RPBS are set out in the RPBS Explanatory Notes.

Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines

Premium Free Dispensing Incentive payments will commence for eligible PBS listed products dispensed from 1 August 2008. Premium Free Dispensing Incentive payments will be available to approved suppliers to dispense a substitutable, premium-free medicine. The payment will be available only for PBS items which attract a Government subsidy. This includes PBS items supplied to DVA entitled consumers.

A number of conditions and criteria apply to receive this payment. Scripts will be assessed for validity and the Premium Free Dispensing Incentive payment will be paid by Medicare Australia. Further information on this payment can be found on the Medicare Australia website at: http://www.medicareaustralia.gov.au/provider/pbs/pharmacists/reforms.shtml#dispensing

8. How Pharmacists Claim Reimbursement: Documents to be Submitted

A claim for pharmaceutical benefits consists of:

- the original and duplicate of a completed Claim for Payment Form;
- the original orders for emergency drug supplies in a separate bundle;
- the originals of all old format PBS prescriptions and authority PBS prescriptions, the Medicare Australia/DVA copies of new format PBS prescriptions and authority PBS prescriptions, and all repeat authorisations, separated into four bundles for benefits supplied to the general public; concessional beneficiaries/Safety Net Concession Card holders; Safety Net Entitlement Card holders and RPBS patients.

PBS prescriptions in each bundle should be in serial number order, with serial number 1 at the top of the bundle.

PBS prescriptions subject to the Safety Net 20 day rule are bundled according to the resulting payment category. For prescription forms with multiple PBS items, where the Safety Net 20 day rule would result in different payment categories for different items, dispensing via 'deferred supply' should be used where necessary to allow all items to be included in the correct bundles.

PBS prescriptions in the wrong bundle may be returned to the pharmacist for clarification. If appropriate, they can be resubmitted in the correct bundle in the next claim period.

Completing the claim form

The claimant's name, address of the pharmacy from which the pharmacist is approved to supply pharmaceutical benefits, approval number, and claim period number should be entered on the Claim for Payment Form. These details should match the latest written information held by Medicare Australia, or payments can be delayed while clarification is sought.

The claim period number should state how many claims have been submitted so far in a calendar year, e.g., the sixth claim submitted by an approved pharmacist in 2005 should have a claim period number of 0506.

The first and last serial numbers given to items in each bundle are to be entered on the Claim for Payment Form.

A total claim amount is not required – this will be calculated by Medicare Australia after the PBS prescriptions have been individually priced.

The declaration must be signed by the pharmacist approved to supply pharmaceutical benefits, unless he/she has made arrangements through Medicare Australia for another pharmacist to sign it.

Lodging claims

A claim may be lodged at any time during the month at the relevant Medicare Australia State office. Unless other arrangements have been made with Medicare Australia, the following conditions apply:

- only one claim period can exist and only one claim can be lodged per month;
- the claim period shall cover pharmaceutical benefits supplied during one month; and
- the claim shall be sent within 30 days from when the benefits were supplied.

Claims for pharmaceutical benefits supplied over 18 months earlier may not be accepted for computer processing. Pharmacists with such claims should contact Medicare Australia.

Reconciliation statements

As mentioned earlier, a pharmacist will receive a PBS reconciliation statement after a claim period has been processed. It provides details of each prescription for each brand of each pharmaceutical benefit item supplied in that claim period.

Reasons for non-payment of any item are coded, with the code numbers explained in the statement.

PBS prescriptions and repeat authorisations not accepted for payment will be returned, with the exception of PBS prescriptions with a dispensed price equal to or less than the patient contribution. Any other items on those PBS prescriptions that have been paid will have been cancelled.

If a PBS prescription was not accepted and can be re-submitted, it must be given a new serial number and included in a subsequent claim period.

If a PBS prescription is finally rejected for payment and a pharmacist is not satisfied with the decision, he/she may apply to the Administrative Appeals Tribunal for a review of that decision.

9. Pricing PBS Prescriptions

Pricing principles

The same pricing principles apply to all PBS prescriptions.

For ready-prepared pharmaceutical benefits, payment is made on the basis of the lowest-priced brand.

For a pharmaceutical benefit not listed as a ready-prepared item, and where a formulation title is stated but no formulary specified, payment is made on the basis of precedence given to formularies by State/Territory legislation.

Prices published in the Schedule do not include any component for goods and services tax (GST).

Further information on pricing PBS prescriptions can be accessed from the booklet titled *Explanation of Current Pricing* on the Medicare Australia's website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

Pricing dates

Ready-prepared pharmaceutical benefits are priced on the first day of April, August and December for items supplied as from each of those days respectively.
Extemporaneously-prepared pharmaceutical benefits and containers are priced on the first day of May each year for items supplied as from the first day of August that year.

Pricing ready-prepared items

For maximum quantities

The price payable for a pharmaceutical benefit is shown in the Schedule against the item. The price is for the maximum quantity available.

If the prescription is for an injectable item and solvent, the price of each is added together, but only one dispensing fee is payable.

The maximum quantity of some pharmaceutical benefits, such as eye drops and oral suspensions, has been determined as a single pack corresponding to the manufacturer's pack. These packs cannot be broken, so if a PBS prescription calls for less, the maximum quantity should be supplied and claimed from Medicare Australia. Packs not to be broken are indicated by a double dagger (‡) in the Schedule.

For lesser quantities

For items where the standard pack is the same as the maximum quantity, and the pack can be broken, the price payable for a lesser quantity is established as follows:

- an amount equal to the dispensing fee, and if applicable the dangerous drug fee, is deducted from the benefit price as shown in the Schedule;
- to this new amount, a wastage percentage is applied, determined from the Wastage Factor Table;
- then the amount equal to the dispensing fee, dangerous drug fee (if applicable), and appropriate container fee, is added.

In no case shall the price for a broken quantity be more than the dispensed price of the Schedule's maximum quantity.

When a standard pack is not the same as the maximum quantity, the price of the pharmaceutical benefit concerned has an asterisk next to it and the standard pack rate is set out in Section 3 of the Schedule. The price payable for the quantity supplied is established by:

- applying the appropriate wastage table percentage to the standard pack rate;
- then adding an amount equivalent to the dispensing fee, the dangerous drug fee where applicable, and the appropriate container fee.

In no case shall the supply of a broken quantity, which is less than the item's maximum quantity, cost more than the dispensed price for the maximum quantity.

No container fee is payable when the quantity of pharmaceutical benefit supplied is more than the quantity contained in the standard pack.

Wastage table percentage

The following Wastage Factor Table is used to calculate the price payable for quantities supplied from the standard pack.

Wastage Factor Table

Column A -	5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100
Column B -	10, 18, 26, 32, 38, 44, 50, 54, 58, 62, 66, 70, 74, 78, 82, 86, 90, 94, 98, 100

The appropriate wastage table percentage is as follows:

- the percentage of the amount supplied from the amount in the standard pack is determined; and
- where this percentage is the same as a percentage listed in Column A of the table, the percentage used is the figure shown in Column B; or
- where the percentage is not the same as a percentage in Column A, then the nearest upward percentage in Column A applies, and the percentage used is the figure in Column B.

For example, 24 tablets are supplied from a standard pack of 100. Thus 24 per cent of the number contained in the standard pack is supplied. As this percentage does not appear in Column A, the next higher (i.e., 25 per cent) is used. Reading down from 25 per cent to Column B, the wastage table percentage is found to be 38 per cent.

Pricing extemporaneously-prepared items

General

The price payable for supplying the maximum quantity of standard formula preparations is shown in the Standard Formulae List.

The following principles apply in determining prices of all pre-priced extemporaneous formulae on the list.

They also apply when a pharmacist elects to price extemporaneous PBS prescriptions outside the list, including exceptional PBS prescriptions.

The amount payable is the sum of:

- the recovery price of each ingredient as shown in the Drug Tariff;
- the price of the appropriate container as shown in the price section; and

- a dispensing fee as shown in the price section.

Pricing of ingredients

When the quantity dispensed is not specified in the Drug Tariff, the recovery price is as follows:

1. determine the basic pricing unit relative to the quantity dispensed by referring to the following table:

Quantity	Basic Pricing Unit
Up to and including 700 mg	100 mg price rate
Over 700 mg and up to and including 1 g	price as if 1 g
Over 1 g and up to and including 7 g	1 g price rate
Over 7 g and up to and including 10 g	price as if 10 g
Over 10 g and up to and including 80 g	10 g price rate
Over 80 g and up to and including 90 g	price as if 80 g
Over 90 g	100 g price rate

2. find the recovery price of the basic pricing unit by applying the following quantity divisors to the recovery price shown for the ingredient in the Drug Tariff:

- 100 g price is 500 g price divided by 5, or 1 kg price divided by 10
- 10 g price is 100 g price plus 12.5 per cent divided by 10
- 1 g price is 10 g price plus 25 per cent divided by 10
- 100 mg price is 1 g price plus 25 per cent divided by 10

1. find the recovery price by multiplying the price of the basic pricing unit – as established in 2 – by the fraction that the quantity dispensed bears to the basic pricing unit.

For pricing purposes the quantity is to be taken to the next upward 50 milligrams or 0.05 millilitres.

The minimum recovery price for any ingredient is one cent. In other cases where a fraction of a cent occurs, the price is to be taken to the nearest cent (a half cent being taken up to the next cent).

In no case shall the recovery price for a quantity of an ingredient exceed the recovery price for a greater quantity of that ingredient.

Where liquids are purchased by weight, the recovery price includes the 'Specific Gravity Factor'.

Special pricing provisions apply to drugs marked '(a)' or '(b)' in the Drug Tariff.

For drugs marked '(a)', the pricing rules shown above apply to quantities up to the quantity listed in the Drug Tariff. Greater quantities are priced on a linear basis: the recovery price is ascertained by multiplying the fraction that the quantity dispensed bears to the quantity listed in the Drug Tariff by the price shown for the quantity listed.

Drugs marked '(b)' are packed sterile or are unstable, and all quantities are priced as if whole pack(s) were required. The recovery price is ascertained by multiplying the fraction that the quantity dispensed bears to the quantity listed in the Drug Tariff, taken to the next whole number, by the price shown for the quantity listed.

Pricing PBS prescriptions where extra ingredients are added to a formula

Where the vehicle is liquid and one or more solid ingredients are added, displacement of the liquid by the solid ingredients is disregarded for pricing purposes.

Containers

When a quantity is for more than the container sizes listed in this Schedule, payment will be made as if that quantity had been supplied in the minimum number of containers necessary to supply that quantity.

A double size container is allowed for bulk powders.

Special provisions for extemporaneous PBS prescriptions outside the Standard Formulae List

If a pharmacist elects to price extemporaneous PBS prescriptions outside the Standard Formulae List, there can be no variation for three months. This applies to all extemporaneously-prepared formulae not on the list, and includes both PBS and RPBS prescriptions.

If a pharmacist does not elect to price out these PBS prescriptions, he/she will be paid at an average reimbursement rate.

Under this system, payment is made on the basis of an average 10 g/mL rate applied to the category of preparation concerned, i.e., the price will be determined by multiplying the appropriate 10 g/mL rate by the number of 10 g/mL units supplied and adding container and dispensing fees. For example, an 80 mL mixture would be priced at eight times the average 10 mL rate for mixtures, with container and dispensing fee added.

The average 10 g/mL rate for each type of preparation is calculated monthly. It applies to PBS prescriptions supplied in the following month.

PBS prescriptions ordering a combination of standard formula preparations fall outside the scope of the Standard Formulae List and therefore are subject to this section.

Any variant to a formula included in the list (adding or deleting an ingredient or varying the dose) takes the formula dispensed outside the list.

When an ingredient is added to a standard formula and the recovery price for the standard formula plus additive under the average price system is less than for the standard formula alone, the pharmacist may have the PBS prescription priced as a basic standard formula item.

10. Miscellaneous

References

This Schedule identifies monographs of the British Pharmacopoeia, the British Pharmaceutical Codex, and the Australian Pharmaceutical Formulary and Handbook by the letters BP, BPC and APF respectively. References to all editions of the BPC and to earlier editions of the BP and APF also include the year of publication or the number of the edition.

Standards

Pharmacists can only supply under the PBS medicines which, or whose ingredients, conform to the standards of composition or purity prescribed. These standards are those specified in the *Therapeutic Goods Act 1989*.

Legislation

Copies of the *National Health Act 1953* and the *National Health (Pharmaceutical Benefits) Regulations 1960* are available from Government AusInfo shops in each capital city. The Act and the Regulations may also be accessed through the Attorney-General's Department website at www.comlaw.gov.au.

Nurse practitioner PBS prescribing

MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED NURSE PRACTITIONERS

From 1 September 2010, nurse practitioners endorsed to prescribe under state or territory legislation can apply for approval as PBS prescribers (*authorised nurse practitioners*). Information for nurse practitioners to become authorised PBS prescribers is available from Medicare Australia.

The medicines listed for prescribing by authorised nurse practitioners are identified by 'NP' in the PBS Schedule. Nurse practitioners must not write PBS prescriptions for other medicines.

PBS prescribing is limited by a nurse practitioner's scope of practice, and state and territory prescribing rights. Prescribing of PBS medicines is also contingent on a prescriber being an *authorised nurse practitioner* and having collaborative arrangements in place, as required by amendments to the *National Health Act 1953*.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister for Health and Ageing regarding medicines for prescribing by authorised nurse practitioners.

Further to prescribing within collaborative arrangements, certain medicines also have additional conditions for prescribing by nurse practitioners, as recommended by the PBAC. These medicines are identified by the codes 'CTO' for continuation therapy only or 'SCM' for prescribing within a shared care model, as outlined below:

- *Continuing therapy only model*

Where the patient's treatment and prescribing of a medicine has been initiated by a medical practitioner, but prescribing is continued by a nurse practitioner. (This is similar to existing arrangements between specialists and medical practitioners for prescribing certain medicines.)

- *Shared care model*

Where care is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed plan to manage the patient, in a patientcentred model of care. The details surrounding shared care arrangements will depend on the practitioners involved, patient needs and the healthcare context.

Some medicines are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their prescriber type. Listing details for the same product may differ between sections and different PBS item codes apply for each prescriber type.

Nurse practitioner PBS prescriptions are identifiable by colour, and include the indicator 'NP' on personalised forms and a tick box on non-personalised (blank) forms.

Prescriptions must include the nurse practitioner's PBS prescriber number. For unrestricted and restricted PBS medicines, midwives/nurse practitioners can use the personalised or non-personalised PBS prescriber forms. For authority required and authority required (streamlined)

PBS medicines, midwives/nurse practitioners can use the authority personalised or non-personalised PBS prescriber forms. Nurse practitioner PBS prescriptions may include repeats.

Regulation 24 applies for nurse practitioner prescribing. A nurse practitioner can direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time, if certain conditions are satisfied.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from Medicare Australia for each prescription. (Refer to Prescribing Medicines — Information for PBS prescribers and Supplying medicines — What Pharmacists Need to Know, for more information on authority prescriptions.)

State and territory requirements: Nurse practitioners may prescribe medicines as private prescriptions according to their state/territory prescribing accreditation. The medicines which can be prescribed differ between states and territories. It is the nurse practitioner's responsibility to ensure adherence to State/Territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS prescriptions.

Midwife PBS prescribing

MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED MIDWIVES

From 1 September 2010, midwives endorsed to prescribe under state or territory legislation can apply for approval as PBS prescribers (*authorisedmidwives*). Information for midwives to become authorised PBS prescribers is available from Medicare Australia.

The medicines listed for prescribing by authorised midwives are identified by 'MW' in the PBS Schedule. Midwives must not write PBS prescriptions for other medicines.

PBS prescribing by midwives is limited by state and territory prescribing rights. It is also contingent on a prescriber being an *authorised midwife* and having collaborative arrangements in place, as required by amendments to the *National Health Act 1953*.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister for Health and Ageing regarding medicines for prescribing by authorised midwives.

Some medicines are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their prescriber type. Listing details for the same product may differ between sections and different PBS item codes apply for each prescriber type.

Midwife PBS prescriptions are identifiable by colour, and include the indicator 'MW' on personalised forms and a tick box on non-personalised (blank) forms. Prescriptions must include the midwife's PBS prescriber number. For unrestricted and restricted PBS medicines, midwives/nurse practitioners can use the personalised or non-personalised PBS prescriber forms. For authority required and authority required (streamlined) PBS medicines, midwives/nurse practitioners can use the authority personalised or non-personalised PBS prescriber forms. Midwife PBS prescriptions may include repeats.

Regulation 24 applies for midwife prescribing. A midwife can direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time, if certain conditions are satisfied.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from Medicare Australia for each prescription. (Refer to Prescribing Medicines—Information for PBS prescribers and Supplying Medicines — What Pharmacists Need to Know, for more information on authority prescriptions.)

State and Territory requirements: Midwives may prescribe medicines as private prescriptions according to their state/territory prescribing accreditation. The medicines which can be prescribed differ between states and territories. It is the midwife's responsibility to ensure adherence to state/territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS prescriptions.

Therapeutic Index

Section 2

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Items Available Under Special Arrangements (s.100)

SYMBOLS USED IN THE SCHEDULE

An asterisk (*) against the dispensed price of a benefit indicates that the manufacturer's pack does not coincide with the maximum quantity.

A double dagger (‡) in the maximum quantity column indicates an item for which the maximum quantity has been specially determined to correspond to the manufacturer's pack and the manufacturer's standard pack should be prescribed and supplied. For any item where a maximum quantity greater than 1 is marked with a double dagger (‡), that maximum quantity should be prescribed and supplied.

A gauge sign (#) against the dispensed price of a benefit indicates that the product is not preconstituted and that an extemporaneously-prepared dispensing fee is included in the dispensed price and, where appropriate, an amount for purified water.

Where a STATE is indicated after a manufacturer's code, that brand may be available only in the State indicated. NSW–(N); Vic–(V); Qld–(Q); SA–(S); WA–(W); Tas–(T).

RESTRICTED BENEFITS

All restricted items have separate headings for authority and non-authority items. In each case these items may be prescribed as pharmaceutical benefits only for use for one of the specified indications. Where more than one indication is specified for an Authority required or Restricted pharmaceutical benefit, each indication is separated from the preceding indication by a semi-colon and commences on the next line. In the case of Authority required (STREAMLINED) items, each indication will also include a four digit streamlined authority code. The drug may be prescribed as a pharmaceutical benefit for a patient who qualifies under any of the specified indications.

A straight line is drawn between entries for different forms and strengths of an item to indicate clearly the different restrictions which apply to these various forms and strengths.

The maximum quantity and/or number of repeats in respect of an item shown in the Schedule may be varied by the Chief Executive Officer of Medicare Australia when approving an Authority Prescription or an Authority to Prescribe. The quantity and number of repeats shown on the authority shall be supplied. (See Explanatory Notes). Payment will be made on the basis of the price shown for that item in the Schedule.

CODES FOR INJECTABLE ITEMS WITH ALLOWABLE SOLVENTS

The entry in this schedule of those pharmaceutical benefit injectable items which require a solvent includes the codes of the items with the relevant solvents. For each such item the code is for the injectable with 10mL sodium chloride injection 9 mg per mL (0.9%).

BRAND EQUIVALENCE

'a' located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Therapeutic Goods Administration. It would thus be expected that these brands may be interchanged without differences in clinical effect.

For other brands of an item, i.e., those not indicated as above, it is unknown whether or not they are equivalent. There may be several reasons for this, such as bioequivalence data not being considered necessary when the products were approved for marketing, or that advice or data have not been forthcoming from sponsors. This does not necessarily suggest a lack of safety or efficacy, but in these circumstances caution should be taken if brands are interchanged.

'b' attached to brand names indicates that these brands are also equivalent, but that it is not known if there is equivalence between brands marked 'a' and brands marked 'b'.

BRAND PREMIUM POLICY

The Brand Premium Policy was introduced on 1 December 1990 to increase price competition by allowing pharmaceutical manufacturers to set their own price on multi-branded items listed on the Pharmaceutical Benefits Scheme and to encourage the development of the generic pharmaceutical industry in Australia. The policy does this by increasing prescribers' and patients' consciousness about the price of drugs. In effect, it makes both groups question whether it is necessary for the patient to pay more for the drugs when a cheaper brand is available. The policy also allows companies to establish prices taking into account competition and consumer acceptance.

The policy operates where there is more than one brand of a particular drug available through the Pharmaceutical Benefits Scheme and where the brands are therapeutically interchangeable. Due to this, the policy mainly applies to out of patent drugs.

Basically the policy operates by:

- the Australian Government subsidising a drug to the level of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium);
- suppliers of other brands of that drug being able to set a price above the price charged by the supplier(s) of the lowest priced brand(s); and
- the patient paying the brand premium which is the price difference between the lowest price brand and the brand prescribed.

If a prescription is written generically or for the lowest priced brand, and the lowest priced brand is supplied, there is no brand premium payable.

'B' located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item.

If a brand of a drug which is subject to a therapeutic group premium also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by 'T' and 'B' respectively.

If a brand of a drug which is subject to a special patient contribution also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by 'S' and 'B' respectively.

THERAPEUTIC GROUP PREMIUM POLICY

The Therapeutic Group Premium Policy was introduced on 1 February 1998 as an extension of the Brand Premium Policy to encourage greater competition between manufacturers of drugs and to make doctors and patients more aware of the costs of medicines.

The Therapeutic Group Premium policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety, efficacy and health outcomes.

Basically the policy operates by:

- the Australian Government subsidising drugs within a defined therapeutic sub-group to the level of the lowest priced drug in the sub-group;
- suppliers of other drugs within that sub-group being able to set prices above the price charged by the supplier(s) of the lowest priced drug; and
- the patient paying the therapeutic group premium which is the price difference between the lowest price drug and the drug prescribed.

'T' located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item.

If a brand of a drug which is subject to a therapeutic group premium also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by 'T' and 'B' respectively.

The success of the Government in controlling prices of products supplied through the Pharmaceutical Benefits Scheme has often been criticised by the pharmaceutical industry. Under both the Brand Premium Policy and the Therapeutic Group Premium Policy, suppliers of multi-branded items and therapeutically similar drugs are able to set their own prices at a level that they think the market will bear. At the same time, the prescriber and the patient can decide whether it is necessary to pay more for a particular brand or drug when a cheaper one is available and is therapeutically interchangeable.

The brand premium or therapeutic group premium does not count toward the patient's safety net.

It should be noted that the brand premium or therapeutic group premium is not a Government charge or revenue. The premium arises from the manufacturer's price and the majority goes to the manufacturer with wholesalers and pharmacists receiving a small percentage.

Emergency Drug Supplies

EMERGENCY DRUG SUPPLIES

Code	Name, Manner of Administration and Form	Max. Qty	Dispensed Price for Max. Qty $		Proprietary Name and Manufacturer	
3451P *NP*	ADRENALINE Injection 1 mg in 1 mL (1 in 1,000)	5	20.34		Link Medical Products Pty Ltd	LM
3453R *NP*	ATROPINE Injection containing atropine sulfate 600 micrograms in 1 mL	10	20.54		Pfizer Australia Pty Ltd	PF
3455W *NP*	CHLORPROMAZINE HYDROCHLORIDE Injection 50 mg in 2 mL	10	20.48		Largactil	SW
or	or					
3456X *NP*	HALOPERIDOL Injection 5 mg in 1 mL	10	22.28		Serenace	QA
3457Y *NP*	BENZTROPINE MESYLATE Injection 2 mg in 2 mL	5	103.59		Cogentin	FK
3458B *NP*	DIAZEPAM Injection 10 mg in 2 mL	5	12.29		Hospira Pty Limited	HH
3460D *NP*	DIHYDROERGOTAMINE MESYLATE Injection 1 mg in 1 mL	5	17.06		Dihydergot	NV
3463G *NP*	DIPHTHERIA and TETANUS VACCINE, ADSORBED, DILUTED FOR ADULT USE Injection 0.5 mL in pre-filled syringe	20	*275.02		ADT Booster	CS
3466K *NP*	FRUSEMIDE Injection 20 mg in 2 mL	5	9.62	[a]	Frusemide Sandoz	SZ
				[a]	Lasix	SW
				[a]	Frusemide-Claris	AE
3467L *NP*	GLUCAGON HYDROCHLORIDE Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	45.63		GlucaGen Hypokit	NO
3472R *NP*	DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL	5	16.22	[a]	Hospira Pty Limited	HH
				[a]	Dexmethsone	AS
or	or					
3470P *NP*	HYDROCORTISONE SODIUM SUCCINATE Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	2	*16.52		Solu-Cortef	PF
or	or					
3471Q *NP*	HYDROCORTISONE SODIUM SUCCINATE Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	15.54		Solu-Cortef	PF
3473T *NP*	HYOSCINE BUTYLBROMIDE Injection 20 mg in 1 mL	5	24.21		Buscopan	BY
3474W *NP*	LIGNOCAINE HYDROCHLORIDE Injection 100 mg in 5 mL	5	37.33		Pfizer Australia Pty Ltd	PF
3475X *NP*	GLYCERYL TRINITRATE Sublingual spray (pump pack) 400 micrograms per dose (200 doses)	‡1	20.13		Nitrolingual Pumpspray	SW
3476Y *NP*	METOCLOPRAMIDE HYDROCHLORIDE Injection 10 mg in 2 mL	10	12.99		Maxolon	VT
or	or					
3477B *NP*	PROCHLORPERAZINE Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	16.82		Stemetil	SW
3478C *NP*	CLONAZEPAM Oral liquid 2.5 mg per mL, 10 mL	‡1	10.73		Rivotril	RO

EMERGENCY DRUG SUPPLIES

Code	Name, Manner of Administration and Form	Max. Qty	Dispensed Price for Max. Qty $		Proprietary Name and Manufacturer	
3479D *NP*	MORPHINE SULFATE Injection 15 mg in 1 mL	5	14.35		Hospira Pty Limited	HH
or	or					
3480E *NP*	MORPHINE SULFATE Injection 30 mg in 1 mL	5	15.77		Hospira Pty Limited	HH
3482G *NP*	NALOXONE HYDROCHLORIDE Injection 2 mg in 5 mL	2	*78.08		Naloxone Min-I-Jet	CS
3484J *NP*	TRAMADOL HYDROCHLORIDE Injection 100 mg in 2 mL	5	13.10	[a]	Tramal 100	CS
				[a]	Tramahexal	SZ
3486L *NP*	BENZYLPENICILLIN Powder for injection 600 mg	10	*42.92		BenPen	CS
or	or					
3485K *NP*	PROCAINE PENICILLIN Injection 1.5 g	5	92.22		Cilicaine	QA
3487M *NP*	BENZYLPENICILLIN Powder for injection 3 g	1	12.75		BenPen	CS
3488N *NP*	PROMETHAZINE HYDROCHLORIDE Injection 50 mg in 2 mL	10	*22.32		Hospira Pty Limited	HH
3489P	METHOXYFLURANE Liquid for inhalation 999.9 mg per g, 3 mL (with inhaler)	1	44.78		Penthrox	NQ
3491R *NP*	TERBUTALINE SULFATE Injection 500 micrograms in 1 mL	5	30.59		Bricanyl	AP
3494X *NP*	VERAPAMIL HYDROCHLORIDE Injection 5 mg in 2 mL	5	12.38		Isoptin	AB
3495Y *NP*	SALBUTAMOL SULFATE Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	‡1	10.12	[a]	Asmol CFC-free	AL
				[a]	Airomir	IA
				[a]	APO-Salbutamol Inhaler	TX
3495Y *NP*	SALBUTAMOL SULFATE Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	‡1	11.28	[a]	Ventolin CFC-free	GK
or	or					
3496B *NP*	SALBUTAMOL SULFATE Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	‡1	12.37	[a]	Asmol 2.5 uni-dose	AF
				[a]	GenRx Salbutamol	GX
				[a]	Butamol 2.5	QA
				[a]	Pharmacor Salbutamol 2.5	CR
				[a]	Salbutamol Sandoz	SZ
				[a]	Salbutamol-GA	GM
3496B *NP*	SALBUTAMOL SULFATE Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	‡1	13.04	[a]	Ventolin Nebules	GK

EMERGENCY DRUG SUPPLIES

Code	Name, Manner of Administration and Form	Max. Qty	Dispensed Price for Max. Qty $		Proprietary Name and Manufacturer	
3497C *NP*	SALBUTAMOL SULFATE Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	‡1	12.70	[a]	Asmol 5 uni-dose	AF
				[a]	GenRx Salbutamol	GX
				[a]	Butamol 5	QA
				[a]	Pharmacor Salbutamol 5	CR
				[a]	Salbutamol Sandoz	SZ
				[a]	Salbutamol-GA	GM
3497C *NP*	SALBUTAMOL SULFATE Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	‡1	13.38	[a]	Ventolin Nebules	GK

Special Pharmaceutical Benefits

SPECIAL PHARMACEUTICAL BENEFITS

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 32.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Reimbursement Price for Max. Qty $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	AMOXYCILLIN								
1888J *NP*	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡1	1	$0.61	#13.23	#13.84	14.67	Amoxil	GK
	AMOXYCILLIN **Authority required** Treatment of infections suspected or proven to be due to a susceptible organism in patients who require a liquid formulation and in whom the syrup formulations are unsuitable.								
9714G *NP*	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡1	1	..	#13.84	#13.84	15.28	Amoxil	GK
	NARATRIPTAN **Caution** Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use. **Authority required** Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8298R *NP*	Tablet 2.5 mg (as hydrochloride)	4	5	$2.78	*25.90	*28.68	26.99	Naramig	GK
	NARATRIPTAN **Caution** Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use. **Authority required** Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where: (a) adverse events have occurred with other suitable PBS-listed drugs; or (b) drug interactions have occurred with other suitable PBS-listed drugs; or (c) drug interactions are expected to occur with other suitable PBS-listed drugs; or (d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or (e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9734H *NP*	Tablet 2.5 mg (as hydrochloride)	4	5	..	*28.68	*28.68	29.77	Naramig	GK
	ZOLMITRIPTAN **Caution** Zolmitriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.								

SPECIAL PHARMACEUTICAL BENEFITS

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 32.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Reimbursement Price for Max. Qty $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Authority required Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8266C *NP*	Tablet 2.5 mg	4	5	$2.76	*25.84	*28.60	26.93	Zomig	AP
	ZOLMITRIPTAN **Caution** Zolmitriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use. **Authority required** Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where: (a) adverse events have occurred with other suitable PBS-listed drugs; or (b) drug interactions have occurred with other suitable PBS-listed drugs; or (c) drug interactions are expected to occur with other suitable PBS-listed drugs; or (d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or (e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9736K *NP*	Tablet 2.5 mg	4	5	..	*28.60	*28.60	29.69	Zomig	AP

PHARMACEUTICAL BENEFITS FOR DENTAL USE

	AMOXYCILLIN								
3310F	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡1	..	$0.61	#13.23	#13.84	14.67	Amoxil	GK

General Pharmaceutical Benefits

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Alimentary tract and metabolism

Stomatological preparations

Stomatological preparations

Antiinfectives and antiseptics for local oral treatment

AMPHOTERICIN

2931G *NP*	Lozenge 10 mg	20	1	..	12.03	13.12		Fungilin	QA

NYSTATIN

3033P *NP*	Oral suspension 100,000 units per mL, 24 mL	‡1	1	..	11.14	12.23		Mycostatin	FM
								Nilstat	QA

Other agents for local oral treatment

BENZYDAMINE HYDROCHLORIDE

Restricted benefit

Radiation induced mucositis.

1121B *NP*	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	‡1	1	..	22.26	23.35		Difflam	IA

Drugs for acid related disorders

Antacids

Combinations and complexes of aluminium, calcium and magnesium compounds

ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE

2157M *NP*	Oral suspension 200 mg-200 mg per 5 mL, 500 mL	2	5	..	*17.70	18.79		Mylanta P	JT

ALUMINIUM HYDROXIDE with MAGNESIUM TRISILICATE and MAGNESIUM HYDROXIDE

2159P *NP*	Oral suspension 250 mg-120 mg-120 mg per 5 mL, 500 mL	2	5	..	*17.70	18.79		Gastrogel	FM

Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)

H_2-receptor antagonists

Note

The base-priced drugs in this therapeutic group are cimetidine, nizatidine and ranitidine hydrochloride (except ranitidine hydrochloride effervescent tablet 150 mg (base) and syrup 150 mg (base) per 10 mL, 300 mL).

CIMETIDINE

Note

Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

1158Y *NP*	Tablet 400 mg	60	5	..	18.48	19.57		Magicul 400	AF
1159B *NP*	Tablet 800 mg	30	5	..	18.48	19.57		Magicul 800	AF

FAMOTIDINE

Note

Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

2487X *NP*	Tablet 20 mg	60	5	..	14.22	15.31	[a]	Ausfam 20	QA
							[a]	Chem mart Famotidine	CH
							[a]	Famotidine Sandoz	SZ

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	GenRx Famotidine	GX
							[a]	Pamacid 20	AF
							[a]	Pepzan	GM
							[a]	Terry White Chemists Famotidine	TW
2488Y *NP*	Tablet 40 mg	30	5	..	14.22	15.31	[a]	Ausfam 40	QA
							[a]	Chem mart Famotidine	CH
							[a]	Famotidine Sandoz	SZ
							[a]	GenRx Famotidine	GX
							[a]	Pamacid 40	AF
							[a]	Pepzan	GM
							[a]	Terry White Chemists Famotidine	TW
				[B]3.84	18.06	15.31	[a]	Pepcidine	MK
	NIZATIDINE								
	Note								
	Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1504E *NP*	Capsule 300 mg	30	5	..	18.43	19.52	[a]	Nizac	LN
							[a]	Tacidine	AF
				[B]5.32	23.75	19.52	[a]	Tazac	AS
1505F *NP*	Capsule 150 mg	60	5	..	18.43	19.52	[a]	Nizac	LN
							[a]	Tacidine	AF
				[B]5.32	23.75	19.52	[a]	Tazac	AS
	RANITIDINE HYDROCHLORIDE								
	Note								
	Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1937Y *NP*	Effervescent tablet 150 mg (base)	60	5	[T]3.16	*20.48	18.41		Zantac	GK
1977C *NP*	Tablet 300 mg (base)	30	5	..	17.30	18.39	[a]	Ausran	QA
							[a]	Chem mart Ranitidine	CH
							[a]	GenRx Ranitidine	GX
							[a]	Rani 2	AF
							[a]	Ranitidine Sandoz	SZ
							[a]	Terry White Chemists Ranitidine	TW
							[a]	Ulcaid	RA
				[B]2.35	19.65	18.39	[a]	Zantac	GK
1978D *NP,MW*	Tablet 150 mg (base)	60	5	..	17.30	18.39	[a]	Ausran	QA
							[a]	Chem mart Ranitidine	CH
							[a]	GenRx Ranitidine	GX
							[a]	Rani 2	AF
							[a]	Ranitidine-PS	FZ
							[a]	Ranitidine Sandoz	SZ
							[a]	Ranoxyl	GM
							[a]	Terry White	TW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Chemists Ranitidine	
							[a]	Ulcaid	RA
				[B]2.35	19.65	18.39	[a]	Zantac	GK
8162N *NP*	Syrup 150 mg (base) per 10 mL, 300 mL	2	5	[T]2.20	*26.72	25.61		Zantac Syrup	GK

RANITIDINE HYDROCHLORIDE

Note

Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

Authority required

Adverse effects occurring with all of the base-priced drugs;

Drug interactions occurring with all of the base-priced drugs;

Drug interactions expected to occur with all of the base-priced drugs;

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

8903N *NP*	Effervescent tablet 150 mg (base)	60	5	..	*20.48	21.57	Zantac	GK
8905Q *NP*	Syrup 150 mg (base) per 10 mL, 300 mL	2	5	..	*26.72	27.81	Zantac Syrup	GK

Prostaglandins

MISOPROSTOL

Caution

Misoprostol is a prostaglandin analogue. It should not be used in pregnant women.

Authority required (STREAMLINED)

2630

Reduction in the incidence of gastrointestinal complications in patients who have a history of peptic ulcer disease and where NSAID therapy is essential;

2631

Duodenal ulcer (including pyloric and stomal ulcers), proven by current or prior x-ray, endoscopy or surgery. The date and the method by which the ulcer was proven must be documented in the patient's medical records when treatment is initiated;

2632

Gastric ulcer, proven by x-ray, endoscopy or surgery within the previous 2 years. The date and the method by which the ulcer was proven must be documented in the patient's medical records when treatment is initiated.

1648R	Tablet 200 micrograms	120	2	..	52.12	35.40	Cytotec	PF

Proton pump inhibitors

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

Restricted benefit

Initial treatment of gastric ulcer.

Note

Helicobacter pylori eradication therapy should be considered.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8886Q *NP*	Tablet (enteric coated), equivalent to 20 mg esomeprazole	30	1	..	30.04	31.13	Nexium	AP

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

Restricted benefit

Healing of gastro-oesophageal reflux disease.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8601Q *NP*	Tablet (enteric coated), equivalent to 40 mg esomeprazole	30	1	..	45.69	35.40	Nexium	AP

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE **Restricted benefit** Maintenance of healed gastro-oesophageal reflux disease; Scleroderma oesophagus; Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion. **Note** No applications for increased maximum quantities will be authorised.								
8600P *NP*	Tablet (enteric coated), equivalent to 20 mg esomeprazole	30	5	..	30.04	31.13		Nexium	AP
	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE **Authority required** Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion; Scleroderma oesophagus. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
3401B *NP*	Tablet (enteric coated), equivalent to 40 mg esomeprazole	30	5	..	45.69	35.40		Nexium	AP
	LANSOPRAZOLE **Restricted benefit** Initial treatment of peptic ulcer. **Note** Helicobacter pylori eradication therapy should be considered. No applications for increased repeats will be authorised. **Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.								
2240X *NP*	Capsule 30 mg	28	1	..	23.45	24.54	[a]	APO-Lansoprazole	TX
							[a]	Lanzopran	RA
							[a]	Zopral	AF
9477T *NP*	Tablet 30 mg (orally disintegrating)	28	1	..	23.45	24.54	[a]	Zoton FasTabs	PF
	LANSOPRAZOLE **Restricted benefit** Gastro-oesophageal reflux disease; Scleroderma oesophagus.								
8198L *NP*	Capsule 15 mg	30	5	..	16.61	17.70		Zopral	AF
9331D *NP*	Tablet 15 mg (orally disintegrating)	28	5	..	15.90	16.99		Zoton FasTabs	PF
	LANSOPRAZOLE **Restricted benefit** Gastro-oesophageal reflux disease; Scleroderma oesophagus.								

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.								
2241Y *NP*	Capsule 30 mg	28	5	..	23.45	24.54	a	APO-Lansoprazole	TX
							a	Lanzopran	RA
							a	Zopral	AF
9478W *NP*	Tablet 30 mg (orally disintegrating)	28	5	..	23.45	24.54	a	Zoton FasTabs	PF
	OMEPRAZOLE **Restricted benefit** Initial treatment of peptic ulcer.								
	Note Helicobacter pylori eradication therapy should be considered. No applications for increased repeats will be authorised.								
	Note Pharmaceutical benefits that have the form omeprazole tablet 20 mg and pharmaceutical benefits that have the form omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.								
8331L *NP*	Tablet 20 mg	30	1	..	20.04	21.13	a	APO-Omeprazole	TX
							a	Chem mart Omeprazole	CH
							a	GenRx Omeprazole	GX
							a	Meprazol	SZ
							a	Omeprazole-GA	GM
							a	Omeprazole generichealth	GQ
							a	Omeprazole-PS	FZ
							a	Omeprazole Ranbaxy	RA
							a	Omeprazole Winthrop	WA
							a	Ozmep	ZP
							a	Terry White Chemists Omeprazole	TW
9109K *NP*	Tablet 20 mg (as magnesium)	30	1	..	20.04	21.13	a	Acimax Tablets	AL
							a	Omepral	PM
				[B]2.23	22.27	21.13	a	Losec Tablets	AP
	OMEPRAZOLE **Restricted benefit** Initial treatment of peptic ulcer.								
	Note Helicobacter pylori eradication therapy should be considered. No applications for increased repeats will be authorised.								
1326T *NP*	Capsule 20 mg	30	1	..	20.04	21.13	a	APO-Omeprazole	TX
							a	Omeprazole Sandoz	HX
							a	Omepro-GA	GM
							a	Pemzo	QA
							a	Pharmacor Omeprazole 20	CR

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Probitor	SZ
	OMEPRAZOLE **Restricted benefit** Gastro-oesophageal reflux disease; Scleroderma oesophagus; Zollinger-Ellison syndrome. **Note** Pharmaceutical benefits that have the form omeprazole tablet 20 mg and pharmaceutical benefits that have the form omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.								
8333N *NP*	Tablet 20 mg	30	5	..	20.04	21.13	[a]	APO-Omeprazole	TX
							[a]	Chem mart Omeprazole	CH
							[a]	GenRx Omeprazole	GX
							[a]	Meprazol	SZ
							[a]	Omeprazole-GA	GM
							[a]	Omeprazole generichealth	GQ
							[a]	Omeprazole Ranbaxy	RA
							[a]	Omeprazole Winthrop	WA
							[a]	Ozmep	ZP
							[a]	Terry White Chemists Omeprazole	TW
9110L *NP*	Tablet 20 mg (as magnesium)	30	5	..	20.04	21.13	[a]	Acimax Tablets	AL
							[a]	Omepral	PM
				[B]2.23	22.27	21.13	[a]	Losec Tablets	AP
	OMEPRAZOLE **Restricted benefit** Gastro-oesophageal reflux disease; Scleroderma oesophagus; Zollinger-Ellison syndrome.								
1327W *NP*	Capsule 20 mg	30	5	..	20.04	21.13	[a]	APO-Omeprazole	TX
							[a]	Omeprazole Sandoz	HX
							[a]	Omepro-GA	GM
							[a]	Pemzo	QA
							[a]	Pharmacor Omeprazole 20	CR
							[a]	Probitor	SZ
8332M *NP*	Tablet 10 mg (as magnesium)	30	5	..	16.02	17.11		Losec Tablets	AP
	PANTOPRAZOLE SODIUM SESQUIHYDRATE **Restricted benefit** Initial treatment of peptic ulcer. **Note** Helicobacter pylori eradication therapy should be considered.								

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note No applications for increased repeats will be authorised.								
8007K *NP*	Tablet (enteric coated), equivalent to 40 mg pantoprazole	30	2	..	21.49	22.58	a	APO-Pantoprazole	TX
							a	Chem mart Pantoprazole	CH
							a	Ozpan	RA
							a	Panthron	GN
							a	Panto	NZ
							a	Pantofast 40	RZ
							a	Pantoloc	NH
							a	Pantoprazole-GA	GM
							a	Pantoprazole generichealth	GQ
							a	Pantoprazole-PS	FZ
							a	Pantoprazole Sandoz	SZ
							a	Salpraz	AF
							a	Somac	NQ
							a	Sozol	QA
							a	Terry White Chemists Pantoprazole	TW
							a	Torzole 40	TA
9423Y *NP*	Sachet containing granules 40 mg	30	2	..	30.71	31.80		Somac	NQ
	PANTOPRAZOLE SODIUM SESQUIHYDRATE **Restricted benefit** Gastro-oesophageal reflux disease.								
	Restricted benefit Scleroderma oesophagus; Zollinger-Ellison syndrome.								
8008L *NP*	Tablet (enteric coated), equivalent to 40 mg pantoprazole	30	5	..	21.49	22.58	a	APO-Pantoprazole	TX
							a	Chem mart Pantoprazole	CH
							a	Ozpan	RA
							a	Panthron	GN
							a	Panto	NZ
							a	Pantofast 40	RZ
							a	Pantoloc	NH
							a	Pantoprazole-GA	GM
							a	Pantoprazole generichealth	GQ
							a	Pantoprazole-PS	FZ
							a	Pantoprazole Sandoz	SZ
							a	Salpraz	AF
							a	Somac	NQ
							a	Sozol	QA
							a	Terry White Chemists Pantoprazole	TW
							a	Torzole 40	TA
8399C	Tablet (enteric coated), equivalent to 20 mg	30	5	..	13.77	14.86	a	APO-Pantoprazole	TX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
NP	pantoprazole							
						[a]	Chem mart Pantoprazole	CH
						[a]	Ozpan	RA
						[a]	Panto	NZ
						[a]	Pantofast 20	RZ
						[a]	Pantoloc	NH
						[a]	Pantoprazole-GA	GM
						[a]	Pantoprazole generichealth	GQ
						[a]	Pantoprazole-PS	FZ
						[a]	Pantoprazole Sandoz	SZ
						[a]	Salpraz	AF
						[a]	Somac	NQ
						[a]	Terry White Chemists Pantoprazole	TW
						[a]	Torzole 20	TA
9424B *NP*	Sachet containing granules 40 mg	30	5	..	30.71	31.80	Somac	NQ
	RABEPRAZOLE SODIUM **Restricted benefit** Initial treatment of peptic ulcer. **Note** Helicobacter pylori eradication therapy should be considered. **Note** No applications for increased repeats will be authorised.							
8509W *NP*	Tablet 20 mg (enteric coated)	30	2	..	33.70	34.79	Pariet	JC
	RABEPRAZOLE SODIUM **Restricted benefit** Gastro-oesophageal reflux disease; Scleroderma oesophagus.							
8507R *NP*	Tablet 10 mg (enteric coated)	28	5	..	33.70	34.79	Pariet	JC
8508T *NP*	Tablet 20 mg (enteric coated)	30	5	..	33.70	34.79	Pariet	JC

Combinations for eradication of Helicobacter pylori

	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE and CLARITHROMYCIN and AMOXYCILLIN **Restricted benefit** Eradication of Helicobacter pylori associated with peptic ulcer disease.							
8738X *NP*	Pack containing 14 tablets (enteric coated) equivalent to 20 mg esomeprazole, 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg	‡1	..	..	65.27	35.40	Nexium Hp7	AP
	OMEPRAZOLE and CLARITHROMYCIN and AMOXYCILLIN **Restricted benefit** Eradication of Helicobacter pylori associated with peptic ulcer disease.							
8272J *NP*	Pack containing 14 capsules omeprazole 20 mg, 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg	‡1	..	..	58.64	35.40	Probitor Hp7	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)								
	SODIUM ALGINATE with CALCIUM CARBONATE and SODIUM BICARBONATE								
2014B *NP*	Oral liquid 1 g-320 mg-534 mg in 20 mL, 500 mL	2	5	..	*14.68	15.77		Gaviscon P	RC
	SUCRALFATE								
2055E *NP*	Tablet equivalent to 1 g anhydrous sucralfate	120	2	..	24.72	25.81	a	Ulcyte	AF
				B2.06	26.78	25.81	a	Carafate	AS

Drugs for functional gastrointestinal disorders

Belladonna and derivatives, plain

Belladonna alkaloids, tertiary amines

ATROPINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1089H *NP*	Injection containing atropine sulfate 600 micrograms in 1 mL	10	1	..	20.54	21.63		Pfizer Australia Pty Ltd	PF

Propulsives

Propulsives

DOMPERIDONE

1347X *NP*	Tablet 10 mg	25	..	..	8.89	9.98		Motilium	JC

METOCLOPRAMIDE HYDROCHLORIDE

1206L *NP,MW*	Injection 10 mg in 2 mL	10	..	..	12.99	14.08		Maxolon	VT
1207M *NP,MW*	Tablet 10 mg	25	..	..	8.20	9.29		Pramin	AF
				B3.02	11.22	9.29		Maxolon	VT

Antiemetics and antinauseants

Antiemetics and antinauseants

Serotonin (5HT $_3$) antagonists

GRANISETRON HYDROCHLORIDE

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

8728J *NP*	Tablet 2 mg (base)	2	..	..	*58.98	35.40		Kytril	HH
8729K *NP*	Concentrated injection 3 mg (base) in 3 mL	1	..	..	37.85	35.40	a	Kytril	HH
				..	*38.79	35.40	a	Granisetron Kabi	PK

GRANISETRON HYDROCHLORIDE

Authority required (STREAMLINED)

3611

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8730L *NP*	Concentrated injection 3 mg (base) in 3 mL	1	..	..	37.85	35.40	a	Kytril	HH
				..	*38.79	35.40	a	Granisetron Kabi	PK
8873B *NP*	Tablet 2 mg (base)	5	1	..	137.84	35.40		Kytril	HH

ONDANSETRON
Restricted benefit
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

8224W *NP*	Tablet 4 mg (as hydrochloride dihydrate)	4	..	..	26.42	27.51	a	APO-Ondansetron	TX
							a	Ondansetron-DRLA	RZ
							a	Ondaz	SZ
							a	Onsetron 4	ZP
							a	Zofran	GK
8225X *NP*	Tablet 8 mg (as hydrochloride dihydrate)	4	..	..	37.73	35.40	a	APO-Ondansetron	TX
							a	Ondansetron-DRLA	RZ
							a	Ondaz	SZ
							a	Onsetron 8	ZP
							a	Zofran	GK
8226Y *NP*	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	1	..	..	16.90	17.99	a	Ondansetron Alphapharm	AF
							a	Ondansetron-Claris	AE
							a	Ondaz	SZ
							a	Onsetron	ZP
							a	Zofran	GK
8227B *NP*	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	1	..	..	23.06	24.15	a	Ondansetron Alphapharm	AF
							a	Ondansetron-Claris	AE
							a	Ondaz	SZ
							a	Onsetron	ZP
							a	Zofran	GK
9441X *NP*	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	‡1	..	..	101.96	35.40		Zofran syrup 50 mL	GK

ONDANSETRON
Restricted benefit
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

Note
Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron wafer 4 mg are equivalent for the purposes of substitution.

5470X *NP*	Tablet (orally disintegrating) 4 mg	4	..	..	26.42	27.51	a	Ondansetron ODT-DRLA	RZ
8410P *NP*	Wafer 4 mg	4	..	..	26.42	27.51	a	Ondaz Zydis	SZ
							a	Zofran Zydis	GK

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ONDANSETRON								
	Restricted benefit								
	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.								
	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.								
	Note								
	Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron wafer 8 mg are equivalent for the purposes of substitution.								
5471Y *NP*	Tablet (orally disintegrating) 8 mg	4	..	..	37.73	35.40	a	Ondansetron ODT-DRLA	RZ
8411Q *NP*	Wafer 8 mg	4	..	..	37.73	35.40	a	Ondaz Zydis	SZ
							a	Zofran Zydis	GK
	ONDANSETRON								
	Authority required (STREAMLINED)								
	3611								
	Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.								
1594X *NP*	Tablet 4 mg (as hydrochloride dihydrate)	10	1	..	54.40	35.40	a	APO-Ondansetron	TX
							a	Ondansetron-DRLA	RZ
							a	Ondansetron Tabs Pfizer	FZ
							a	Ondaz	SZ
							a	Onsetron 4	ZP
							a	Zilfojim 4	DO
							a	Zofran	GK
1595Y *NP*	Tablet 8 mg (as hydrochloride dihydrate)	10	1	..	81.32	35.40	a	APO-Ondansetron	TX
							a	Ondansetron-DRLA	RZ
							a	Ondansetron Tabs Pfizer	FZ
							a	Ondaz	SZ
							a	Onsetron 8	ZP
							a	Zilfojim 8	DO
							a	Zofran	GK
1596B *NP*	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	1	..	..	16.90	17.99	a	Ondansetron Alphapharm	AF
							a	Ondansetron-Claris	AE
							a	Ondaz	SZ
							a	Onsetron	ZP
							a	Zofran	GK
1597C *NP*	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	1	..	..	23.06	24.15	a	Ondansetron Alphapharm	AF
							a	Ondansetron-Claris	AE
							a	Ondaz	SZ
							a	Onsetron	ZP
							a	Zofran	GK
8233H *NP*	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	‡1	1	..	101.96	35.40		Zofran syrup 50 mL	GK
	ONDANSETRON								
	Authority required (STREAMLINED)								
	3611								
	Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron wafer 4 mg are equivalent for the purposes of substitution.								
5472B *NP*	Tablet (orally disintegrating) 4 mg	10	1	..	54.40	35.40	a	Ondansetron ODT-DRLA	RZ
8412R *NP*	Wafer 4 mg	10	1	..	54.40	35.40	a	Ondaz Zydis	SZ
							a	Zofran Zydis	GK

ONDANSETRON
Authority required (STREAMLINED)
3611
Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.

Note
Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron wafer 8 mg are equivalent for the purposes of substitution.

5473C *NP*	Tablet (orally disintegrating) 8 mg	10	1	..	81.32	35.40	a	Ondansetron ODT-DRLA	RZ
8413T *NP*	Wafer 8 mg	10	1	..	81.32	35.40	a	Ondaz Zydis	SZ
							a	Zofran Zydis	GK

PALONOSETRON
Restricted benefit
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Note
No applications for increased maximum quantities will be authorised. Palonosetron is not PBS-subsidised for administration with oral 5-HT3 antagonists.

5295Q *NP*	Injection 250 micrograms (as hydrochloride) in 5 mL	1	..	..	47.86	35.40		Aloxi	TS

TROPISETRON HYDROCHLORIDE
Restricted benefit
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

2745L *NP*	Capsule 5 mg (base)	2	..	..	50.72	35.40		Navoban	NV
2746M *NP*	I.V. injection 5 mg (base) in 5 mL	1	..	..	29.29	30.38		Navoban	NV

Other antiemetics

APREPITANT
Note
Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Authority required (STREAMLINED)
3619
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone, where any 1 of the following chemotherapy agents are to be administered:
(a) altretamine;
(b) carmustine;
(c) cisplatin when a single dose constitutes a cycle of chemotherapy;
(d) cyclophosphamide at a dose of 1500 mg per square metre per day or greater;
(e) dacarbazine;
(f) procarbazine when a single dose constitutes a cycle of chemotherapy;
(g) streptozocin.
No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy;

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	3620								
	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer, in combination with a 5HT3 antagonist and dexamethasone, where cyclophosphamide and an anthracycline are to be co-administered.								
	No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy;								
	3621								
	Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or vomiting where any 1 of the following intravenous chemotherapy agents is to be administered:								
	(a) arsenic trioxide;								
	(b) azacitidine;								
	(c) carboplatin;								
	(d) cyclophosphamide at a dose of less than 1500 mg per square metre per day;								
	(e) cytarabine at a dose of greater than 1 g per square metre per day;								
	(f) dactinomycin;								
	(g) daunorubicin;								
	(h) doxorubicin;								
	(i) epirubicin;								
	(j) fotemustine;								
	(k) idarubicin;								
	(l) ifosfamide;								
	(m) irinotecan;								
	(n) melphalan;								
	(o) methotrexate at a dose of 250 mg to 1 g per square metre;								
	(p) oxaliplatin;								
	(q) raltitrexed.								
	No more than one pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8808N *NP*	Pack containing 1 capsule 125 mg and 2 capsules 80 mg	‡1	5	..	138.89	35.40		Emend	MK
	PROCHLORPERAZINE								
	Caution								
	Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.								
	Note								
	As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.								
2369Q *NP*	Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	..	..	16.82	17.91		Stemetil	SW
2893G *NP*	Tablet containing prochlorperazine maleate 5 mg	25	..	..	9.46	10.55	[a]	APO-Prochlorperazine	TX
							[a]	Pharmacor Prozine 5	CR
							[a]	ProCalm	QA
							[a]	Prochlorperazine-GA	GM
							[a]	Prochlorperazine GH	GQ
							[a]	Prochlorperazine-PS	FZ
							[a]	Stemzine	AV
				[B]3.45	12.91	10.55	[a]	Stemetil	SW
2895J *NP*	Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5	‡1	2	..	19.93	21.02		Stemetil	SW

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Bile and liver Therapy									
Bile therapy									
Bile acid preparations									
	URSODEOXYCHOLIC ACID **Authority required (STREAMLINED)** ***1700*** Primary biliary cirrhosis. **Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8448P *NP*	Capsule 250 mg	200	2	..	*372.60	35.40		Ursofalk	OA
Laxatives									
Contact laxatives									
	BISACODYL **Restricted benefit** Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function; Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities; For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult; Patients receiving palliative care; Terminal malignant neoplasia; Anorectal congenital abnormalities; Megacolon.								
1258F *NP*	Suppositories 10 mg, 12	3	4	..	*18.33	19.42		Petrus Bisacodyl Suppositories	PP
1259G *NP*	Tablet 5 mg	200	2	..	14.11	15.20		Bisalax	AS
								Lax-Tab	AE
1260H *NP*	Suppositories 10 mg, 10	3	5	..	*20.94	22.03	a	Petrus Bisacodyl Suppositories	PP
				B1.50	*22.44	22.03	a	Dulcolax	BY
Bulk producers									
	STERCULIA with FRANGULA BARK **Restricted benefit** Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function; Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities; For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult; Patients receiving palliative care; Terminal malignant neoplasia; Anorectal congenital abnormalities; Megacolon.								
1104D *NP*	Granules 620 mg-80 mg per g (62%-8%), 500 g	‡1	1	..	26.37	27.46		Normacol Plus	NE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Osmotically acting laxatives								
	LACTULOSE								
	Restricted benefit								
	Hepatic coma or precoma (chronic porto-systemic encephalopathy);								
	Constipation in patients with malignant neoplasia.								
3064G *NP*	Mixture 3.34 g per 5 mL, 500 mL	‡1	5	..	12.01	13.10	a	Actilax	AF
							a	Genlac	QA
							a	GenRx Lactulose	GX
							a	Lac-Dol	GM
							a	Lactocur	SZ
				B1.20	13.21	13.10	a	Duphalac	AB
	MACROGOL 3350								
	Restricted benefit								
	Constipation in patients with malignant neoplasia;								
	Chronic constipation or faecal impaction not adequately controlled with first line interventions such as bulk-forming agents;								
	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies;								
	Patients receiving palliative care.								
3416T *NP*	Powder for oral solution 510 g	‡1	5	..	20.55	21.64	a	MediHealth ClearLax	ON
							a	OsmoLax	KY
							a	your pharmacy Clear Laxative	OY
8612G *NP*	Sachets containing powder for solution 13.125 g with electrolytes, 30	‡1	5	..	20.55	21.64		Movicol	NE
	Enemas								
	BISACODYL								
	Restricted benefit								
	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;								
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;								
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;								
	Patients receiving palliative care;								
	Terminal malignant neoplasia;								
	Anorectal congenital abnormalities;								
	Megacolon.								
1263L *NP*	Enemas 10 mg in 5 mL, 25	‡1	2	..	37.94	35.40		Bisalax	AS
	SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE								
	Restricted benefit								
	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;								
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;								
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;								
	Patients receiving palliative care;								
	Terminal malignant neoplasia;								
	Anorectal congenital abnormalities;								
	Megacolon.								
2091C *NP*	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2	2	..	*32.28	33.37	a	Micolette	AE
							a	Microlax	JT

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Other laxatives								
	GLYCEROL								
	Restricted benefit								
	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;								
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;								
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;								
	Patients receiving palliative care;								
	Terminal malignant neoplasia;								
	Anorectal congenital abnormalities;								
	Megacolon.								
2555L *NP*	Suppositories 700 mg (for infants), 12	3	5	..	*19.47	20.56		Petrus Pharmaceuticals Pty Ltd	PP
2556M *NP*	Suppositories 1.4 g (for children), 12	3	5	..	*19.89	20.98		Petrus Pharmaceuticals Pty Ltd	PP
2557N *NP*	Suppositories 2.8 g (for adults), 12	3	5	..	*20.40	21.49		Petrus Pharmaceuticals Pty Ltd	PP

Antidiarrheals, intestinal antiinflammatory/ antiinfective agents

Intestinal antiinfectives

Antibiotics

	NYSTATIN								
1696G *NP*	Tablet 500,000 units	50	..	..	17.98	19.07		Nilstat	QA
1699K *NP*	Capsule 500,000 units	50	..	..	17.98	19.07		Nilstat	QA
	VANCOMYCIN								
	Authority required								
	Antibiotic associated pseudomembranous colitis due to Clostridium difficile which is unresponsive to metronidazole;								
	Antibiotic associated pseudomembranous colitis due to Clostridium difficile where there is intolerance to metronidazole.								
	Note								
	Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.								
3113W	Capsule 125 mg (125,000 i.u.) vancomycin activity	40	..	..	*232.26	35.40		Vancocin	AS
3114X	Capsule 250 mg (250,000 i.u.) vancomycin activity	40	..	..	*440.06	35.40		Vancocin	AS

Electrolytes with carbohydrates

Oral rehydration salt formulations

	ELECTROLYTE REPLACEMENT (ORAL)								
	Note								
	Each sachet contains sodium chloride 470 mg, potassium chloride 300 mg, sodium acid citrate 530 mg and glucose 3.56 g.								
3196F *NP*	Sachets containing powder for oral solution 4.9 g, 10	‡1	..	..	12.92	14.01	[a]	O.R.S.	AS
							[a]	Repalyte New Formulation	SW
							[a]	restore O.R.S.	GM

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Antipropulsives									
Antipropulsives									
	DIPHENOXYLATE HYDROCHLORIDE with ATROPINE SULFATE								
2501P *NP*	Tablet 2.5 mg-25 micrograms	20	..	..	8.48	9.57	a	Lofenoxal	HC
				[B]1.72	10.20	9.57	a	Lomotil	BI
	LOPERAMIDE HYDROCHLORIDE								
1571Q *NP*	Capsule 2 mg	12	..	..	8.46	9.55	a	Gastro-Stop Loperamide	AS
				[B]0.89	9.35	9.55	a	Imodium	JT
Intestinal antiinflammatory agents									
Corticosteroids acting locally									
	HYDROCORTISONE ACETATE **Restricted benefit** Proctitis; Ulcerative colitis. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1502C *NP*	Rectal foam 90 mg per applicatorful, 14 applications, aerosol 21.1 g	2	3	..	*37.08	35.40		Colifoam	AS
	PREDNISOLONE SODIUM PHOSPHATE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1920C *NP*	Retention enema equivalent to 20 mg prednisolone in 100 mL	28	3	..	*211.34	35.40		Predsol	QA
	PREDNISOLONE SODIUM PHOSPHATE **Restricted benefit** Proctitis; Ulcerative colitis. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2554K *NP*	Suppositories equivalent to 5 mg prednisolone, 10	3	3	..	*41.70	35.40		Predsol	QA
Aminosalicylic acid and similar agents									
	BALSALAZIDE SODIUM **Authority required (STREAMLINED)** ***1708*** Ulcerative colitis where hypersensitivity to sulfonamides exists; ***1709*** Ulcerative colitis where intolerance to sulfasalazine exists. **Note** Not for the treatment of Crohn disease.								

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8845M *NP*	Capsule 750 mg	180	5	..	124.85	35.40	Colazide	PK

MESALAZINE
Authority required (STREAMLINED)
1708
Ulcerative colitis where hypersensitivity to sulfonamides exists;

1709
Ulcerative colitis where intolerance to sulfasalazine exists;

2268
Crohn disease where hypersensitivity to sulfonamides exists;

2269
Crohn disease where intolerance to sulfasalazine exists.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1611T *NP*	Tablet 250 mg (enteric coated)	100	5	..	93.43	35.40	Mesasal	GK
2214M *NP*	Tablet 500 mg (prolonged release)	200	5	..	*297.44	35.40	Pentasa	FP
2234N *NP*	Sachet containing prolonged release granules, 1 g per sachet	120	5	..	330.67	35.40	Pentasa	FP
2287J *NP*	Sachet containing prolonged release granules, 2 g per sachet	60	5	..	312.30	35.40	Pentasa	FP
3413P *NP*	Tablet 1 g (prolonged release)	120	5	..	*330.68	35.40	Pentasa	FP
8731M *NP*	Tablet 500 mg (enteric coated)	200	5	..	*297.44	35.40	Salofalk	OA

MESALAZINE
Authority required (STREAMLINED)
1708
Ulcerative colitis where hypersensitivity to sulfonamides exists;

1709
Ulcerative colitis where intolerance to sulfasalazine exists.

Note
Not for the treatment of Crohn disease.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8598M *NP*	Sachet containing granules, 500 mg per sachet	200	5	..	*297.44	35.40	Salofalk	OA
8599N *NP*	Sachet containing granules, 1 g per sachet	100	5	..	279.63	35.40	Salofalk	OA
9206M *NP*	Sachet containing granules, 1.5 g per sachet	60	5	..	244.92	35.40	Salofalk	OA
9353G *NP*	Tablet 1.2 g (prolonged release)	60	5	..	220.99	35.40	Mezavant	ZI

MESALAZINE
Restricted benefit
Acute episode of mild to moderate ulcerative proctitis.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Not for the treatment of Crohn disease.							
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
5461K *NP*	Suppository (moulded) 1 g	30	1	..	136.39	35.40	Salofalk	OA
8752P *NP*	Suppository 1 g	30	1	..	136.39	35.40	Pentasa	FP
	MESALAZINE **Authority required (STREAMLINED)** ***1707*** Acute episode of mild to moderate ulcerative colitis.							
	Note Not for the treatment of Crohn disease.							
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
8616L *NP*	Enemas 2 g in 60 mL, 7	4	1	..	*336.22	35.40	Salofalk	OA
8617M *NP*	Enemas 4 g in 60 mL, 7	4	1	..	*445.90	35.40	Salofalk	OA
8753Q *NP*	Enemas 1 g in 100 mL, 7	4	1	..	*336.22	35.40	Pentasa	FP
8768L *NP*	Rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g	4	1	..	*336.22	35.40	Salofalk	OA
	OLSALAZINE SODIUM **Authority required (STREAMLINED)** ***1708*** Ulcerative colitis where hypersensitivity to sulfonamides exists;							
	1709 Ulcerative colitis where intolerance to sulfasalazine exists.							
	Note Not for the treatment of Crohn disease.							
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1728Y *NP*	Capsule 250 mg	100	5	..	61.41	35.40	Dipentum	UC
8086N *NP*	Tablet 500 mg	100	5	..	103.29	35.40	Dipentum	UC
	SULFASALAZINE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2093E *NP*	Tablet 500 mg	200	5	..	*50.28	35.40	Salazopyrin	PF
2096H	Tablet 500 mg (enteric coated)	200	5	..	*54.24	35.40 [a]	Pyralin EN	FZ

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP				[B]1.84	*56.08	35.40	[a]	Salazopyrin-EN	PF

SULFASALAZINE

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9208P	Tablet 500 mg	200	11	..	*50.28	35.40		Salazopyrin	PF
9209Q	Tablet 500 mg (enteric coated)	200	11	..	*54.24	35.40	[a]	Pyralin EN	FZ
				[B]1.84	*56.08	35.40	[a]	Salazopyrin-EN	PF

Digestives, incl. enzymes

Digestives, incl. enzymes
Enzyme preparations

PANCREATIC EXTRACT

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5453B *NP*	Granules (enteric coated) providing not less than 5,000 BP units of lipase activity per 100 mg, 20 g	3	10	..	*141.78	35.40		Creon Micro	AB
8020D *NP*	Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity	500	10	..	*183.67	35.40		Creon 10,000	AB
8021E *NP*	Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity	200	10	..	*147.74	35.40		Creon 25,000	AB
9412J *NP*	Capsule (containing enteric coated minimicrospheres) providing not less than 40,000 BP units of lipase activity	200	10	..	*229.96	35.40		Creon 40,000	AB

PANCREATIC EXTRACT

Restricted benefit

For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

5454C	Granules (enteric coated) providing not less than 5,000 BP units of lipase activity per 100 mg, 20 g	3	21	..	*141.78	35.40		Creon Micro	AB
9226N	Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity	500	21	..	*183.67	35.40		Creon 10,000	AB
9227P	Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity	200	21	..	*147.74	35.40		Creon 25,000	AB
9413K	Capsule (containing enteric coated minimicrospheres) providing not less than 40,000 BP units of lipase activity	200	21	..	*229.96	35.40		Creon 40,000	AB

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	PANCRELIPASE							
	Note							
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8366H *NP*	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity	200	10	..	*137.90	35.40	Panzytrat 25000	TM
	PANCRELIPASE							
	Restricted benefit For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
9229R	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity	200	21	..	*137.90	35.40	Panzytrat 25000	TM

Drugs used in diabetes

Insulins and analogues

Insulins and analogues for injection, fast-acting

	INSULIN ASPART							
8435Y *NP*	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	*264.22	35.40	NovoRapid FlexPen	NF
							NovoRapid Penfill 3 mL	NO
8571D *NP*	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	*159.27	35.40	NovoRapid	NO
	INSULIN GLULISINE							
1921D *NP*	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	*264.22	35.40	Apidra	AV
							Apidra SoloStar	SW
9224L *NP*	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	*159.27	35.40	Apidra	SW
	INSULIN LISPRO							
8084L *NP*	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	*159.27	35.40	Humalog	LY
8212F *NP*	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	*264.22	35.40	Humalog	LY
							Humalog KwikPen	KP
	INSULIN NEUTRAL							
1531N *NP*	Injection (human) 100 units per mL, 10 mL	5	2	..	*133.82	35.40	Actrapid	NO
							Humulin R	LY
1713E *NP*	Injection (bovine) 100 units per mL, 10 mL	5	2	..	*172.02	35.40	Hypurin Neutral	AS
1762R *NP*	Injections (human) 100 units per mL, 3 mL, 5	5	1	..	*224.32	35.40	Actrapid Penfill 3 mL	NO
							Humulin R	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Insulins and analogues for injection, intermediate-acting							
	INSULIN ISOPHANE (N.P.H.)							
1533Q *NP*	Injection (human) 100 units per mL, 10 mL	5	2	..	*133.82	35.40	Humulin NPH	LY
							Protaphane	NO
1711C *NP*	Injection (bovine) 100 units per mL, 10 mL	5	2	..	*172.02	35.40	Hypurin Isophane	AS
1761Q *NP*	Injections (human) 100 units per mL, 3 mL, 5	5	1	..	*224.32	35.40	Humulin NPH	LY
							Protaphane InnoLet	NI
							Protaphane Penfill 3 mL	NO
	Insulins and analogues for injection, intermediate-acting combined with fast-acting							
	INSULIN ASPART—INSULIN ASPART PROTAMINE SUSPENSION							
8609D *NP*	Injections (human analogue) 100 units (30 units-70 units) per mL, 3 mL, 5	5	1	..	*264.22	35.40	NovoMix 30 FlexPen	NF
							NovoMix 30 Penfill 3 mL	NO
	INSULIN LISPRO—INSULIN LISPRO PROTAMINE SUSPENSION							
8390N *NP*	Injections (human analogue) 100 units (25 units-75 units) per mL, 3 mL, 5	5	1	..	*264.22	35.40	Humalog Mix25	LY
							Humalog Mix25 KwikPen	KP
8874C *NP*	Injections (human analogue) 100 units (50 units-50 units) per mL, 3 mL, 5	5	1	..	*264.22	35.40	Humalog Mix50	LY
							Humalog Mix50 KwikPen	KP
	INSULIN NEUTRAL—INSULIN ISOPHANE (N.P.H.), (MIXED) (Biphasic Isophane)							
1426C *NP*	Injection (human) 100 units (30 units-70 units) per mL, 10 mL	5	2	..	*133.82	35.40	Humulin 30/70	LY
1763T *NP*	Injections (human) 100 units (30 units-70 units) per mL, 3 mL, 5	5	1	..	*224.32	35.40	Humulin 30/70	LY
							Mixtard 30/70 InnoLet	NI
							Mixtard 30/70 Penfill 3 mL	NO
2062M *NP*	Injections (human) 100 units (50 units-50 units) per mL, 3 mL, 5	5	1	..	*224.32	35.40	Mixtard 50/50 Penfill 3 mL	NO
	Insulins and analogues for injection, long-acting							
	INSULIN DETEMIR **Restricted benefit** Type 1 diabetes.							
9040T *NP*	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	*432.72	35.40	Levemir FlexPen	NF
							Levemir Penfill	NO
	INSULIN GLARGINE							
9039R *NP*	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	*432.72	35.40	Lantus	SW
							Lantus SoloStar	AV

Blood glucose lowering drugs, excl. insulins

Biguanides

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	METFORMIN HYDROCHLORIDE								
1801T *NP*	Tablet 850 mg	60	5	..	11.66	12.75	a	APO-Metformin 850	TX
							a	Chem mart Metformin	CH
							a	Diaformin 850	AF
							a	Formet 850	QA
							a	GenRx Metformin	GX
							a	Glucobete 850	DO
							a	Metformin 850	CR
							a	Metformin-GA	GM
							a	Metformin generichealth	GQ
							a	Metformin Ranbaxy	RA
							a	Metformin Sandoz	SZ
							a	Terry White Chemists Metformin	TW
				B0.87	12.53	12.75	a	Glucophage	MQ
				B1.41	13.07	12.75	a	Diabex 850	AL
2430X *NP*	Tablet 500 mg	100	5	..	11.66	12.75	a	APO-Metformin 500	TX
							a	Chem mart Metformin	CH
							a	Diaformin	AF
							a	Formet 500	QA
							a	GenRx Metformin	GX
							a	Glucobete 500	DO
							a	Metformin 500	CR
							a	Metformin-GA	GM
							a	Metformin generichealth	GQ
							a	Metformin Ranbaxy	RA
							a	Metformin Sandoz	SZ
							a	Terry White Chemists Metformin	TW
				B0.87	12.53	12.75	a	Glucophage	MQ
				B1.41	13.07	12.75	a	Diabex	AL
3439B *NP*	Tablet 1 g (extended release)	60	5	..	14.82	15.91		Diabex XR 1000	AL
8607B *NP*	Tablet 1 g	90	5	..	15.57	16.66	a	APO-Metformin 1000	TX
							a	Chem mart Metformin 1000	CH
							a	Diaformin 1000	AF
							a	Formet 1000	QA
							a	Glucobete 1000	DO
							a	Metformin-GA	GM
							a	Metformin generichealth 1000	GQ
							a	Metformin Ranbaxy 1000	RA
							a	Metformin Sandoz	SZ

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Pharmacor Metformin 1000	CR
							[a]	Terry White Chemists Metformin 1000	TW
				[B]1.43	17.00	16.66	[a]	Diabex 1000	AL
9435N *NP*	Tablet 500 mg (extended release)	120	5	..	14.82	15.91	[a]	Diabex XR	AL
							[a]	Diaformin XR	AF
							[a]	Metex XR	QA

Sulfonamides, urea derivatives

GLIBENCLAMIDE
Caution
Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

2939Q *NP*	Tablet 5 mg	100	5	..	11.39	12.48	[a]	Glimel	AF
				[B]1.44	12.83	12.48	[a]	Daonil	SW

GLICLAZIDE
Caution
Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

2449X *NP*	Tablet 80 mg	100	5	..	13.16	14.25	[a]	Chem mart Gliclazide	CH
							[a]	GenRx Gliclazide	GX
							[a]	Glyade	AF
							[a]	Mellihexal	SZ
							[a]	Nidem	QA
							[a]	Terry White Chemists Gliclazide	TW
8535F *NP*	Tablet 30 mg (modified release)	100	5	..	13.35	14.44	[a]	APO-Gliclazide MR	TX
							[a]	Chem mart Gliclazide MR	CH
							[a]	Glyade MR	AF
							[a]	Oziclide MR	RA
							[a]	Terry White Chemists Gliclazide MR	TW
9302N *NP*	Tablet 60 mg (modified release)	60	5	..	14.75	15.84		Diamicron 60mg MR	SE

GLIMEPIRIDE
Caution
Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

8450R *NP*	Tablet 1 mg	30	5	..	8.28	9.37	[a]	APO-Glimepiride	TX
							[a]	Aylide 1	AF
							[a]	Diapride 1	QA
							[a]	Dimirel	AV
							[a]	Glimepiride GA 1	GM
							[a]	Glimepiride Sandoz	SZ
							[a]	Pharmacor Glimepiride 1	CR
				[B]2.06	10.34	9.37	[a]	Amaryl	SW
8451T *NP*	Tablet 2 mg	30	5	..	10.00	11.09	[a]	APO-Glimepiride	TX

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Aylide 2	AF
							[a]	Diapride 2	QA
							[a]	Dimirel	AV
							[a]	Glimepiride GA 2	GM
							[a]	Glimepiride Sandoz	SZ
							[a]	Pharmacor Glimepiride 2	CR
				[B]2.07	12.07	11.09	[a]	Amaryl	SW
8452W *NP*	Tablet 4 mg	30	5	..	12.02	13.11	[a]	APO-Glimepiride	TX
							[a]	Aylide 4	AF
							[a]	Diapride 4	QA
							[a]	Dimirel	AV
							[a]	Glimepiride GA 4	GM
							[a]	Glimepiride Sandoz	SZ
							[a]	Pharmacor Glimepiride 4	CR
				[B]2.06	14.08	13.11	[a]	Amaryl	SW
8533D *NP*	Tablet 3 mg	30	5	..	11.00	12.09	[a]	APO-Glimepiride	TX
							[a]	Aylide 3	AF
							[a]	Diapride 3	QA
							[a]	Dimirel	AV
							[a]	Glimepiride GA 3	GM
							[a]	Glimepiride Sandoz	SZ
							[a]	Pharmacor Glimepiride 3	CR
				[B]2.04	13.04	12.09	[a]	Amaryl	SW
	GLIPIZIDE **Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
2440K *NP*	Tablet 5 mg	100	5	..	12.27	13.36	[a]	Melizide	AF
				[B]3.83	16.10	13.36	[a]	Minidiab	PF

Combinations of oral blood glucose lowering drugs

METFORMIN HYDROCHLORIDE with GLIBENCLAMIDE
Caution
Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

8810Q *NP*	Tablet 500 mg-2.5 mg	90	5	..	14.49	15.58	Glucovance 500mg/2.5mg AL
8811R *NP*	Tablet 500 mg-5 mg	90	5	..	15.61	16.70	Glucovance 500mg/5mg AL
8838E *NP*	Tablet 250 mg-1.25 mg	90	5	..	12.48	13.57	Glucovance 250mg/1.25mg AL

ROSIGLITAZONE with METFORMIN
Note
Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with a sulfonylurea (triple oral therapy) or an insulin or a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required
Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin and where a sulfonylurea is contraindicated or not tolerated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	like peptide-1 is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.							
9059T *NP*	Tablet containing 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride	56	5	..	64.32	35.40	Avandamet	GK
9060W *NP*	Tablet containing 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride	56	5	..	66.96	35.40	Avandamet	GK
9061X *NP*	Tablet containing 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride	56	5	..	93.99	35.40	Avandamet	GK
9062Y *NP*	Tablet containing 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride	56	5	..	96.63	35.40	Avandamet	GK
	SITAGLIPTIN with METFORMIN **Note** Sitagliptin with metformin fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1. **Authority required (STREAMLINED)** ***3543*** Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records. **Authority required (STREAMLINED)** ***3149*** Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.							
9449H *NP*	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 500 mg metformin hydrochloride	56	5	..	93.99	35.40	Janumet	MK
9450J *NP*	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 850 mg metformin hydrochloride	56	5	..	95.87	35.40	Janumet	MK
9451K *NP*	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride	56	5	..	96.63	35.40	Janumet	MK
	VILDAGLIPTIN with METFORMIN **Note** Vildagliptin with metformin fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1. **Authority required (STREAMLINED)** ***3543*** Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	like peptide-1 is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records; ***3686*** Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.							
5474D *NP*	Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride	60	5	..	97.17	35.40	Galvumet 50/500	NV
5475E *NP*	Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride	60	5	..	99.17	35.40	Galvumet 50/850	NV
5476F *NP*	Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride	60	5	..	100.00	35.40	Galvumet 50/1000	NV

Alpha glucosidase inhibitors

ACARBOSE

8188Y *NP*	Tablet 50 mg	90	5	..	34.53	35.40	Glucobay 50	BN
8189B *NP*	Tablet 100 mg	90	5	..	45.53	35.40	Glucobay 100	BN

Thiazolidinediones

PIOGLITAZONE

Note

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

3540

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Authority required (STREAMLINED)

3541

Combination therapy with insulin

Type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Authority required (STREAMLINED)								
	3542								
	Triple oral combination therapy with metformin and a sulfonylurea Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with maximally tolerated doses of metformin and a sulfonylurea. The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.								
8694N *NP*	Tablet 15 mg (as hydrochloride)	28	5	..	53.00	35.40	a	Acpio 15	QA
							a	Actos	LY
							a	APOTEX-Pioglitazone	TX
							a	Chem mart Pioglitazone	CH
							a	Pharmacor Pioglitazone 15	CR
							a	Pioglitazone-GA	GM
							a	Pioglitazone generichealth 15	GQ
							a	Pioglitazone Sandoz	SZ
							a	Pizaccord	RA
							a	Terry White Chemists Pioglitazone	TW
							a	Vexazone	AF
8695P *NP*	Tablet 30 mg (as hydrochloride)	28	5	..	77.62	35.40	a	Acpio 30	QA
							a	Actos	LY
							a	APOTEX-Pioglitazone	TX
							a	Chem mart Pioglitazone	CH
							a	Pharmacor Pioglitazone 30	CR
							a	Pioglitazone-GA	GM
							a	Pioglitazone generichealth 30	GQ
							a	Pioglitazone Sandoz	SZ
							a	Pizaccord	RA
							a	Terry White Chemists Pioglitazone	TW
							a	Vexazone	AF
8696Q *NP*	Tablet 45 mg (as hydrochloride)	28	5	..	99.01	35.40	a	Acpio 45	QA
							a	Actos	LY
							a	APOTEX-Pioglitazone	TX
							a	Chem mart Pioglitazone	CH
							a	Pharmacor Pioglitazone 45	CR
							a	Pioglitazone-GA	GM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							[a] Pioglitazone generichealth 45	GQ
							[a] Pioglitazone Sandoz	SZ
							[a] Pizaccord	RA
							[a] Terry White Chemists Pioglitazone	TW
							[a] Vexazone	AF

ROSIGLITAZONE

Note

Rosiglitazone maleate is not PBS-subsidised as monotherapy or in combination with metformin and a sulfonylurea (triple oral therapy) or an insulin or a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required

Dual oral combination therapy with metformin or a sulfonylurea
Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

8689H *NP*	Tablet 4 mg (as maleate)	28	5	..	61.52	35.40	Avandia	GK
8690J *NP*	Tablet 8 mg (as maleate)	28	5	..	91.19	35.40	Avandia	GK

Dipeptidyl peptidase 4 (DPP-4) inhibitors

LINAGLIPTIN

Note

Linagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

3540

Dual oral combination therapy with metformin or a sulfonylurea
Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

3387G *NP*	Tablet 5 mg	30	5	..	96.62	35.40	Trajenta	BY

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	SAXAGLIPTIN							
	Note							
	Saxagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.							
	Authority required (STREAMLINED)							
	3540							
	Dual oral combination therapy with metformin or a sulfonylurea Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.							
8983T *NP*	Tablet 5 mg (as hydrochloride)	28	5	..	91.19	35.40	Onglyza	BQ
	SITAGLIPTIN							
	Note							
	Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.							
	Authority required (STREAMLINED)							
	3540							
	Dual oral combination therapy with metformin or a sulfonylurea Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.							
9180E *NP*	Tablet 25 mg (as phosphate monohydrate)	28	5	..	91.19	35.40	Januvia	MK
9181F *NP*	Tablet 50 mg (as phosphate monohydrate)	28	5	..	91.19	35.40	Januvia	MK
9182G *NP*	Tablet 100 mg (as phosphate monohydrate)	28	5	..	91.19	35.40	Januvia	MK
	VILDAGLIPTIN							
	Note							
	Vildagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.							
	Authority required (STREAMLINED)							
	3540							
	Dual oral combination therapy with metformin or a sulfonylurea Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.							
3415R *NP*	Tablet 50 mg	60	5	..	97.24	35.40	Galvus	NV

Other blood glucose lowering drugs, excl. insulins

EXENATIDE

Note

Exenatide is not PBS-subsidised as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone) or a dipeptidyl peptidase 4 inhibitor (gliptin).

Authority required (STREAMLINED)

3540

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Authority required (STREAMLINED)

3542

Triple oral combination therapy with metformin and a sulfonylurea

Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Note

Special Pricing Arrangements apply.

3423E *NP*	Injection solution 5 micrograms per dose in pre-filled pen, 60 doses	1	5	..	176.39	35.40	Byetta 5 microgram	LY
3424F *NP*	Injection solution 10 micrograms per dose in pre-filled pen, 60 doses	1	5	..	176.39	35.40	Byetta 10 microgram	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Vitamins									
Vitamin A and D, incl. combinations of the two									
Vitamin D and analogues									
	CALCITRIOL **Authority required (STREAMLINED)** ***1165*** Hypocalcaemia due to renal disease; ***1166*** Hypoparathyroidism; ***1167*** Hypophosphataemic rickets; ***1467*** Vitamin D-resistant rickets; ***2636*** Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
2502Q *NP*	Capsule 0.25 microgram	100	3	..	37.31	35.40	a	Calciprox	GN
							a	Calcitriol-GA	GM
							a	Calcitriol-PS	FZ
							a	Calcitriol Sandoz	SZ
							a	GenRx Calcitriol	GX
							a	Kosteo	QA
							a	Rocaltrol	RO
							a	Sical	AF
Vitamin B_1, plain and in combination with vitamin B_6 and vitamin B_{12}									
Vitamin B_1, plain									
	THIAMINE HYDROCHLORIDE **Authority required (STREAMLINED)** ***2384*** Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person.								
1070H *NP*	Tablet 100 mg	100	2	..	11.50	12.59		Betamin	SW
Mineral supplements									
Calcium									
Calcium									
	CALCIUM **Authority required (STREAMLINED)** ***2212*** Hyperphosphataemia associated with chronic renal failure.								
3116B *NP*	Tablet (chewable) 500 mg (as carbonate)	240	1	..	*30.46	31.55		Cal-Sup	IA
3117C *NP*	Tablet 600 mg (as carbonate)	240	1	..	22.20	23.29		Calci-Tab 600	AE
Potassium									
Potassium									
	POTASSIUM CHLORIDE								
2642C	Tablet 600 mg (sustained release)	200	1	..	*12.88	13.97	a	Duro-K	NM

Alimentary tract and metabolism

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP									
				[B]2.94	*15.82	13.97	[a]	Slow-K	NV
				..	12.89	13.98		Span-K	AS
	POTASSIUM CHLORIDE with POTASSIUM BICARBONATE								
3012M *NP*	Effervescent tablet 14 mmol potassium and 8 mmol chloride	60	1	..	15.14	16.23		Chlorvescent	AS

Other mineral supplements

Magnesium

MAGNESIUM

Authority required

Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person;

Chronic renal disease in an Aboriginal or a Torres Strait Islander person.

5146W *NP*	Tablet 37.4 mg (as aspartate dihydrate)	50	5	..	13.70	14.79		Mag-Sup	PP

Anabolic agents for systemic use

Anabolic steroids

Estren derivatives

NANDROLONE DECANOATE

Authority required

Monotherapy for osteoporosis, where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval;

Monotherapy for osteoporosis, where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval;

Monotherapy for osteoporosis, where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval;

Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004;

Patients on long-term treatment with corticosteroids.

Note

Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.

1671Y	Injection 50 mg in 1 mL, disposable syringe	1	7	..	21.20	22.29		Deca-Durabolin	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Blood and blood forming organs

Antithrombotic agents

Antithrombotic agents

Vitamin K antagonists

WARFARIN SODIUM

Caution

The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

2209G *NP*	Tablet 2 mg	50	2	..	12.77	13.86	Coumadin	QA
2211J *NP*	Tablet 5 mg	50	2	..	14.03	15.12	Coumadin	QA
							Marevan	FM
2843P *NP*	Tablet 1 mg	50	2	..	12.42	13.51	Coumadin	QA
							Marevan	FM
2844Q *NP*	Tablet 3 mg	50	2	..	12.69	13.78	Marevan	FM

Heparin group

DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)

2816F *NP*	Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	20	..	..	*108.88	35.40	Fragmin	PF
5445N *NP*	Injection 12,500 units (anti-Xa) in 0.5 mL single dose pre-filled syringe	10	1	..	125.69	35.40	Fragmin	PF
8269F *NP*	Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe	10	1	..	90.99	35.40	Fragmin	PF
8271H *NP*	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	10	1	..	68.38	35.40	Fragmin	PF
8603T *NP*	Injection 2,500 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	20	..	..	*104.74	35.40	Fragmin	PF

DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)

Restricted benefit

Haemodialysis.

1229Q *NP*	Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe	20	3	..	*175.56	35.40	Fragmin	PF
1296F *NP*	Injection 12,500 units (anti-Xa) in 0.5 mL single dose pre-filled syringe	20	3	..	*241.28	35.40	Fragmin	PF
8641T *NP*	Injection 2,500 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	20	3	..	*104.74	35.40	Fragmin	PF
8642W *NP*	Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	20	3	..	*108.88	35.40	Fragmin	PF
8643X *NP*	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	20	3	..	*130.34	35.40	Fragmin	PF

DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)

Restricted benefit

Management of symptomatic venous thromboembolism in a patient with a solid tumour(s).

Note

No applications for increased maximum quantities will be authorised.

8956J *NP*	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	30	5	..	*192.30	35.40	Fragmin	PF
8957K *NP*	Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe	30	5	..	*255.06	35.40	Fragmin	PF
8958L	Injection 12,500 units (anti-Xa) in 0.5 mL single	30	5	..	*349.71	35.40	Fragmin	PF

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP	dose pre-filled syringe								
8959M *NP*	Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe	30	5	..	*414.75	35.40		Fragmin	PF
8960N *NP*	Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe	30	5	..	*493.59	35.40		Fragmin	PF
	ENOXAPARIN SODIUM								
8262W *NP*	Injection 60 mg (6,000 i.u. anti-Xa) in 0.6 mL pre-filled syringe	10	1	..	79.68	35.40		Clexane	SW
8263X *NP*	Injection 80 mg (8,000 i.u. anti-Xa) in 0.8 mL pre-filled syringe	10	1	..	90.70	35.40		Clexane	SW
8264Y *NP*	Injection 100 mg (10,000 i.u. anti-Xa) in 1 mL pre-filled syringe	10	1	..	109.08	35.40		Clexane	SW
8510X *NP*	Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe	20	..	..	*108.88	35.40		Clexane	SW
8558K *NP*	Injection 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe	20	..	..	*104.74	35.40		Clexane	SW
9195Y *NP*	Solution for injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL	20	..	..	*108.88	35.40		Clexane	SW
	ENOXAPARIN SODIUM **Restricted benefit** Haemodialysis.								
5434B *NP*	Injection 80 mg (8,000 i.u. anti-Xa) in 0.8 mL pre-filled syringe	20	3	..	*174.98	35.40		Clexane	SW
5435C *NP*	Injection 100 mg (10,000 i.u. anti-Xa) in 1 mL pre-filled syringe	20	3	..	*211.08	35.40		Clexane	SW
8639Q *NP*	Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe	20	3	..	*108.88	35.40		Clexane	SW
8640R *NP*	Injection 60 mg (6,000 i.u. anti-Xa) in 0.6 mL pre-filled syringe	20	3	..	*152.94	35.40		Clexane	SW
8716R *NP*	Injection 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe	20	3	..	*104.74	35.40		Clexane	SW
9196B *NP*	Solution for injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL	20	3	..	*108.88	35.40		Clexane	SW
	HEPARIN SODIUM								
1076P *NP*	Injection 35,000 units in 35 mL	12	5	..	*278.58	35.40		Hospira Pty Limited	HH
1463B *NP*	Injection (preservative-free) 5,000 units in 5 mL	50	5	..	66.93	35.40		Pfizer Australia Pty Ltd	PF
1466E *NP*	Injection 5,000 units in 0.2 mL	5	5	..	15.48	16.57		Hospira Pty Limited	HH

Platelet aggregation inhibitors excl. heparin

ABCIXIMAB
Authority required (STREAMLINED)
1716
Patients undergoing percutaneous coronary balloon angioplasty;
1717
Patients undergoing percutaneous coronary atherectomy;
1718
Patients undergoing percutaneous coronary stent placement.

8048N	I.V. injection 10 mg in 5 mL	3	..	..	*1453.11	35.40		ReoPro	LY
	ASPIRIN								
1010E *NP*	Tablet 300 mg (dispersible)	96	1	..	8.50	9.59		Solprin	RC
8202Q *NP*	Tablet 100 mg	112	1	..	8.03	9.12	a	Mayne Pharma Aspirin	YT

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
				[B]1.29	9.32	9.12	[a]	Astrix	YN

CLOPIDOGREL

Authority required (STREAMLINED)

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin;

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;

1721

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;

1722

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin;

1723

Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;

1724

Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs.

Note

Not for prophylaxis of DVT or peripheral arterial disease.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

5436D *NP*	Tablet 75 mg	28	5	..	50.05	35.40	[a]	Clopidogrel-DRLA	RZ
8358X *NP*	Tablet 75 mg (as hydrogen sulfate)	28	5	..	50.05	35.40	[a]	APO-Clopidogrel	TX
							[a]	Chem mart Clopidogrel	CH
							[a]	Clopidogrel RBX	RA
							[a]	Clopidogrel Sandoz	SZ
							[a]	Clopidogrel Winthrop	WA
							[a]	Iscover	BQ
							[a]	Piax	AF
							[a]	Plavix	SW
							[a]	Terry White Chemists Clopidogrel	TW
9354H *NP*	Tablet 75 mg (as besilate)	28	5	..	50.05	35.40	[a]	Clopidogrel Actavis	TA
							[a]	Clopidogrel-GA	GM
							[a]	Clopidogrel GH	GQ
							[a]	Clopidogrel-PS	FZ
							[a]	Clovix 75	QA

CLOPIDOGREL

Authority required (STREAMLINED)

3879

Treatment of acute coronary syndrome (myocardial infarction or unstable angina) in combination with aspirin;

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	3146 Treatment in combination with aspirin following cardiac stent insertion. **Note** Not for prophylaxis of DVT or peripheral arterial disease. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9317J *NP*	Tablet 75 mg (as hydrogen sulfate)	28	5	..	50.05	35.40	a	Clopidogrel Winthrop	WA
							a	Iscover	BQ
							a	Plavix	SW
	CLOPIDOGREL with ASPIRIN **Authority required (STREAMLINED)** ***3880*** Treatment of acute coronary syndrome (myocardial infarction or unstable angina); ***3219*** Treatment following cardiac stent insertion; ***1722*** Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin. **Note** Not for prophylaxis of DVT or peripheral arterial disease. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9296G *NP*	Tablet 75 mg (as hydrogen sulfate)-100 mg	30	5	..	74.87	35.40	a	Clopidogrel Winthrop plus aspirin	WA
							a	CoPlavix	SW
							a	DuoCover	BQ
	DIPYRIDAMOLE **Restricted benefit** Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events: (1) as adjunctive therapy with low-dose aspirin; or (2) where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding; or (3) where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8335Q *NP*	Capsule 200 mg (sustained release)	60	5	..	36.96	35.40		Persantin SR	BY
	DIPYRIDAMOLE with ASPIRIN **Restricted benefit** Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8382E *NP*	Capsule 200 mg (sustained release)-25 mg	60	5	..	37.19	35.40		Asasantin SR	BY

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	EPTIFIBATIDE ACETATE							
	Authority required (STREAMLINED)							
	1884							
	Patients undergoing non-urgent percutaneous intervention with intracoronary stenting.							
8683B	Solution for I.V. injection 20 mg (base) in 10 mL	2	..	..	*262.54	35.40	Integrilin	MK
8684C	Solution for I.V. infusion 75 mg (base) in 100 mL	3	..	..	*1020.36	35.40	Integrilin	MK
	PRASUGREL							
	Authority required (STREAMLINED)							
	3208							
	Treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention in combination with aspirin.							
	Note							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9495R *NP*	Tablet 5 mg (as hydrochloride)	28	5	..	96.43	35.40	Effient	LY
9496T *NP*	Tablet 10 mg (as hydrochloride)	28	5	..	106.43	35.40	Effient	LY
	TICLOPIDINE HYDROCHLORIDE							
	Caution							
	Severe neutropenia is common in the early months of therapy. Haematological monitoring should be undertaken at commencement and every two weeks in the first four months of therapy.							
	Authority required (STREAMLINED)							
	1719							
	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin;							
	1720							
	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;							
	1721							
	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;							
	1260							
	Patients established on this drug as a pharmaceutical benefit prior to 1 November 1999.							
	Note							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2095G *NP*	Tablet 250 mg	60	5	..	121.93	35.40	Tilodene	AF
	TIROFIBAN HYDROCHLORIDE							
	Authority required (STREAMLINED)							
	1729							
	Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes;							
	1730							
	Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours;							
	1275							
	Patients with non-Q-wave myocardial infarction.							
	Note							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8350L *NP*	Solution concentrate for I.V. infusion 12.5 mg (base) in 50 mL	1	2	..	363.11	35.40	Aggrastat	AS

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Enzymes							
	RETEPLASE (Recombinant plasminogen activator) **Restricted benefit** Treatment of acute myocardial infarction within 6 hours of onset of attack. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8253J *NP*	Pack containing 2 vials powder for injection 10 units, 2 single use pre-filled syringes with solvent, 2 reconstitution spikes and 2 needles	‡1	..	..	2066.96	35.40	Rapilysin 10 U	TA
	TENECTEPLASE **Restricted benefit** Treatment of acute myocardial infarction within 12 hours of onset of attack. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8526R *NP*	Powder for injection 40 mg with solvent	1	..	..	1960.76	35.40	Metalyse	BY
8527T *NP*	Powder for injection 50 mg with solvent	1	..	..	2057.06	35.40	Metalyse	BY
	Direct thrombin inhibitors							
	BIVALIRUDIN TRIFLUOROACETATE **Authority required (STREAMLINED)** ***3075*** A patient undergoing percutaneous coronary intervention.							
8844L	Powder for I.V. injection 250 mg (base)	1	..	..	671.75	35.40	Angiomax	XM
	DABIGATRAN ETEXILATE **Authority required** Prevention of venous thromboembolism in a patient undergoing total hip replacement. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9318K *NP*	Capsule 75 mg (as mesilate)	20	1	..	*81.16	35.40	Pradaxa	BY
9319L *NP*	Capsule 110 mg (as mesilate)	20	1	..	*81.16	35.40	Pradaxa	BY
	DABIGATRAN ETEXILATE **Authority required** Prevention of venous thromboembolism in a patient undergoing total hip replacement. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** No applications for increased maximum quantities and/or repeats will be authorised for the pack of 60 capsules.							
9320M *NP*	Capsules 75 mg (as mesilate), 60	‡1	..	..	228.21	35.40	Pradaxa	BY
9321N *NP*	Capsules 110 mg (as mesilate), 60	‡1	..	..	228.21	35.40	Pradaxa	BY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	DABIGATRAN ETEXILATE **Authority required** Prevention of venous thromboembolism in a patient undergoing total knee replacement. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
9322P *NP*	Capsule 75 mg (as mesilate)	20	..	..	*81.16	35.40	Pradaxa	BY
9323Q *NP*	Capsule 110 mg (as mesilate)	20	..	..	*81.16	35.40	Pradaxa	BY

Other antithrombotic agents

	APIXABAN **Authority required** Prevention of venous thromboembolism in a patient undergoing total knee replacement who requires up to 10 days of therapy; Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 10 days of therapy. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
5500L *NP*	Tablet 2.5 mg	20	..	..	101.14	35.40	Eliquis	BQ
	APIXABAN **Authority required** Prevention of venous thromboembolism in a patient undergoing total knee replacement who requires up to 15 days of therapy; Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 15 days of therapy. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
5054B *NP*	Tablet 2.5 mg	30	..	..	148.66	35.40	Eliquis	BQ
	APIXABAN **Authority required** Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 30 days of therapy. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
5061J *NP*	Tablet 2.5 mg	60	..	..	279.89	35.40	Eliquis	BQ

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	FONDAPARINUX SODIUM **Authority required (STREAMLINED)** ***2005*** Prevention of venous thromboembolic events in patients undergoing major hip surgery; ***2006*** Prevention of venous thromboembolic events in patients undergoing total knee replacement. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8775W *NP*	Injection 2.5 mg in 0.5 mL single dose pre-filled syringe	7	..	..	*140.54	35.40	Arixtra	GK
	RIVAROXABAN **Authority required** Prevention of venous thromboembolism in a patient undergoing total hip replacement. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9465E *NP*	Tablets 10 mg, 10	‡1	1	..	101.14	35.40	Xarelto	BN
9466F *NP*	Tablet 10 mg	15	1	..	148.66	35.40	Xarelto	BN
	RIVAROXABAN **Authority required** Prevention of venous thromboembolism in a patient undergoing total hip replacement. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** No applications for increased maximum quantities and/or repeats will be authorised for the 30 tablet pack.							
9467G *NP*	Tablets 10 mg, 30	‡1	..	..	279.89	35.40	Xarelto	BN
	RIVAROXABAN **Authority required** Prevention of venous thromboembolism in a patient undergoing total knee replacement. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
9468H *NP*	Tablets 10 mg, 10	‡1	..	..	101.14	35.40	Xarelto	BN
9469J *NP*	Tablet 10 mg	15	..	..	148.66	35.40	Xarelto	BN

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Antihemorrhagics									
Antifibrinolytics									
Amino acids									
	TRANEXAMIC ACID								
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2180R *NP*	Tablet 500 mg	100	2	..	51.68	35.40		Cyklokapron	PF
Antianemic preparations									
Iron preparations									
Iron bivalent, oral preparations									
	FERROUS FUMARATE								
8985X *NP*	Tablet 200 mg (equivalent to 65.7 mg iron)	60	1	..	11.62	12.71		Ferro-tab	AE
	FERROUS SULFATE								
8815Y *NP*	Oral liquid 30 mg per mL, 250 mL	‡1	2	..	19.35	20.44		Ferro-Liquid	AE
Iron trivalent, parenteral preparations									
	IRON POLYMALTOSE COMPLEX								
2593L *NP*	Injection 100 mg (iron) in 2 mL	5	..	..	49.57	35.40	[a]	Ferrosig	SI
							[a]	Ferrum H	AS
	IRON SUCROSE								
	Authority required (STREAMLINED)								
	2070 Iron deficiency anaemia, in combination with either epoetin alfa or darbepoetin alfa, in patients undergoing chronic haemodialysis who have had a documented hypersensitivity reaction to iron polymaltose and in whom continued intravenous iron therapy is appropriate.								
8807M *NP*	Concentrate for solution for infusion 2.7 g (equivalent to 100 mg iron (III)) in 5 mL	5	..	..	139.48	35.40		Venofer	AS
Iron in combination with folic acid									
	FERROUS FUMARATE with FOLIC ACID								
9011G *NP*	Tablet 310 mg (equivalent to 100 mg iron)-350 micrograms	60	1	..	12.79	13.88		Ferro-f-tab	AE
Vitamin B_{12} and folic acid									
Vitamin B_{12} (cyanocobalamin and derivatives)									
	HYDROXOCOBALAMIN								
	Restricted benefit								
	Pernicious anaemia;								
	Other proven vitamin B_{12} deficiencies;								
	Prophylaxis after gastrectomy.								
	Note								
	One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B_{12} deficiencies.								
9048F *NP*	Injection 1 mg (as chloride) in 1 mL	3	..	..	14.84	15.93	[a]	Hydroxo-B12	AS
							[a]	Neo-B12	HH

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Folic acid and derivatives								
	FOLIC ACID								
2958Q *NP*	Tablet 500 micrograms	200	..	..	*13.78	14.87		Megafol 0.5	AF
	FOLIC ACID **Note** The 5 mg strength tablet should be used in malabsorption states only.								
1437P *NP*	Tablet 5 mg	200	1	..	*14.02	15.11		Megafol 5	AF
	Blood substitutes and perfusion solutions								
	Blood and related products								
	Blood substitutes and plasma protein fractions								
	GELATIN - SUCCINYLATED								
8444K *NP*	I.V. infusion 20 g per 500 mL, 500 mL	3	..	..	*45.75	35.40		Gelofusine	BR
	HYDROXYETHYL STARCH 130/0.4								
9487H *NP*	I.V. infusion 30 g per 500 mL, 500 mL	3	..	..	*45.75	35.40		Voluven 6%	PK
	POLYGELINE								
2334W *NP*	I.V. infusion 17.5 g per 500 mL (3.5%) with electrolytes, 500 mL	3	..	..	*45.75	35.40		Haemaccel	AE
	I.V. solutions								
	Solutions for parenteral nutrition								
	GLUCOSE								
2245E *NP*	I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	1	..	*22.82	23.91	[a]	B. Braun Australia Pty Ltd	BR
							[a]	Baxter Healthcare Pty Ltd	BX
							[a]	Fresenius Kabi Australia Pty Limited	PK
9444C *NP*	I.V. infusion 139 mmol (anhydrous) per 500 mL (5%), 500 mL	5	1	..	*17.87	18.96	[a]	B. Braun Australia Pty Ltd	BR
							[a]	Fresenius Kabi Australia Pty Limited	PK
9445D *NP*	I.V. infusion 278 mmol (anhydrous) per 500 mL (10%), 500 mL	5	1	..	*17.87	18.96		Fresenius Kabi Australia Pty Limited	PK
9474P *NP*	I.V. infusion 69.5 mmol (anhydrous) per 250 mL (5%), 250 mL	5	1	..	*23.67	24.76	[a]	B. Braun Australia Pty Ltd	BR
							[a]	Glucose 5% Freeflex	PK
	Solutions affecting the electrolyte balance								
	ELECTROLYTE REPLACEMENT SOLUTION								
3199J *NP*	I.V. infusion 1 L	2	1	..	*21.96	23.05		Plasma-Lyte 148	BX
	SODIUM CHLORIDE								
2260Y	I.V. infusion 513 mmol per L (3%), 1 L	2	1	..	*12.12	13.21		Baxter Healthcare	BX

Blood and blood forming organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP								Pty Ltd	
2264E *NP*	I.V. infusion 154 mmol per L (0.9%), 1 L	5	1	..	*15.92	17.01	a	B. Braun Australia Pty Ltd	BR
							a	Baxter Healthcare Pty Ltd	BX
							a	Fresenius Kabi Australia Pty Limited	PK
9392H *NP*	I.V. infusion 77 mmol per 500 mL (0.9%), 500 mL	5	1	..	*13.02	14.11	a	B. Braun Australia Pty Ltd	BR
							a	Fresenius Kabi Australia Pty Limited	PK
9473N *NP*	I.V. infusion 38.5 mmol per 250 mL (0.9%), 250 mL	5	1	..	*16.37	17.46	a	B. Braun Australia Pty Ltd	BR
							a	Sodium Chloride 0.9% Freeflex	PK
	SODIUM CHLORIDE COMPOUND								
2266G *NP*	I.V. infusion 1 L	4	1	..	*30.02	31.11		Baxter Healthcare Pty Ltd	BX
	SODIUM CHLORIDE with GLUCOSE								
2278X *NP*	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%-2.5%), 500 mL	5	1	..	*28.77	29.86		Baxter Healthcare Pty Ltd	BX
2279Y *NP*	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	1	..	*28.77	29.86		Baxter Healthcare Pty Ltd	BX
2281C *NP*	I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	1	..	*23.52	24.61		Baxter Healthcare Pty Ltd	BX
	SODIUM LACTATE COMPOUND								
2286H *NP*	I.V. infusion 1 L	5	1	..	*15.52	16.61	a	B. Braun Australia Pty Ltd	BR
							a	Baxter Healthcare Pty Ltd	BX
							a	Fresenius Kabi Australia Pty Limited	PK
9416N *NP*	I.V. infusion 500 mL	5	1	..	*12.82	13.91	a	B. Braun Australia Pty Ltd	BR
							a	Fresenius Kabi Australia Pty Limited	PK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Cardiovascular system

Cardiac therapy

Cardiac glycosides

Digitalis glycosides

DIGOXIN

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1322N *NP*	Tablet 250 micrograms	100	1	..	10.71	11.80	a	Sigmaxin	FM
				B2.94	13.65	11.80	a	Lanoxin	QA
2605D *NP*	Tablet 62.5 micrograms	200	1	..	10.42	11.51	a	Sigmaxin-PG	FM
				B2.95	13.37	11.51	a	Lanoxin-PG	QA
3164M *NP*	Oral solution for children 50 micrograms per mL, 60 mL	2	3	..	*41.12	35.40		Lanoxin	QA

Antiarrhythmics, class I and III

Antiarrhythmics, class IA

DISOPYRAMIDE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2923W *NP*	Capsule 100 mg	100	5	..	29.13	30.22		Rythmodan	SW
2924X *NP*	Capsule 150 mg	100	5	..	46.51	35.40		Rythmodan	SW

Antiarrhythmics, class IB

LIGNOCAINE HYDROCHLORIDE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2875H *NP*	Injection 100 mg in 5 mL	5	..	..	37.33	35.40		Pfizer Australia Pty Ltd	PF
2876J *NP*	Infusion 500 mg in 5 mL	10	..	..	29.59	30.68		Xylocard 500	AP

Antiarrhythmics, class IC

FLECAINIDE ACETATE

Caution

Flecainide acetate should be avoided in patients with poor cardiac function.

Restricted benefit

Serious supra-ventricular cardiac arrhythmias;

Serious ventricular cardiac arrhythmias where treatment is initiated in a hospital (in-patient or out-patient).

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1088G *NP*	Tablet 50 mg	60	5	..	37.75	35.40		Tambocor	IA
1090J *NP*	Tablet 100 mg	60	5	..	44.69	35.40	a	Flecatab	AF

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Tambocor	IA

Antiarrhythmics, class III

AMIODARONE

Caution

Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity.
Regular monitoring of hepatic and thyroid function is recommended.

Restricted benefit

Severe cardiac arrhythmias.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2343H *NP*	Tablet containing amiodarone hydrochloride 200 mg	30	5	..	18.22	19.31	[a]	Amiodarone Sandoz	SZ
							[a]	Aratac 200	AF
							[a]	Chem mart Amiodarone	CH
							[a]	Cordarone X 200	SW
							[a]	GenRx Amiodarone	GX
							[a]	Rithmik 200	QA
							[a]	Terry White Chemists Amiodarone	TW
2344J *NP*	Tablet containing amiodarone hydrochloride 100 mg	30	5	..	13.04	14.13	[a]	Amiodarone Sandoz	SZ
							[a]	Aratac 100	AF
							[a]	Cordarone X 100	SW

SOTALOL HYDROCHLORIDE

Restricted benefit

Severe cardiac arrhythmias.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2043M *NP*	Tablet 160 mg	60	5	..	20.02	21.11	[a]	Cardol	AF
							[a]	Chem mart Sotalol	CH
							[a]	GenRx Sotalol	GX
							[a]	Solavert	QA
							[a]	Sotalol Sandoz	SZ
							[a]	Terry White Chemists Sotalol	TW
				[B]3.40	23.42	21.11	[a]	Sotacor	FM
8398B *NP*	Tablet 80 mg	60	5	..	12.77	13.86	[a]	GenRx Sotalol	GX
							[a]	Solavert	QA
							[a]	Sotalol Sandoz	SZ
				[B]3.40	16.17	13.86	[a]	Sotacor	FM

Cardiac stimulants excl. cardiac glycosides
Adrenergic and dopaminergic agents

ADRENALINE

1016L *NP*	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	20.34	21.43		Link Medical Products Pty Ltd	LM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ADRENALINE								
	Authority required Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who: (a) has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply; or (b) has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis; Continuing sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug.								
	Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)								
	Note Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time. No repeats will be issued.								
	Caution EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.								
3408J *NP*	I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40		Anapen Junior	LM
3409K *NP*	I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40		Anapen	LM
8697R *NP*	I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40		EpiPen Jr.	AL
8698T *NP*	I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40		EpiPen	AL

Vasodilators used in cardiac diseases

Organic nitrates

	GLYCERYL TRINITRATE								
1459T *NP*	Tablets 600 micrograms, 100	‡1	5	..	14.83	15.92	[a]	Lycinate	FM
				[B]2.94	17.77	15.92	[a]	Anginine Stabilised	QA
1515R *NP*	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	27.32	28.41		Transiderm-Nitro 25	NV
1516T *NP*	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	33.81	34.90		Transiderm-Nitro 50	NV
8010N *NP*	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	27.32	28.41		Nitro-Dur 5	MK
8011P *NP*	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	33.81	34.90		Nitro-Dur 10	MK
8026K *NP*	Transdermal patch releasing approximately 15 mg per 24 hours	30	5	..	33.81	34.90		Nitro-Dur 15	MK
8027L *NP*	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	27.32	28.41		Minitran 5	IA
8028M *NP*	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	33.81	34.90		Minitran 10	IA
8119H *NP*	Transdermal patch releasing approximately 15 mg per 24 hours	30	5	..	33.81	34.90		Minitran 15	IA
	GLYCERYL TRINITRATE **Note** The spray should not be inhaled.								
8171C *NP*	Sublingual spray (pump pack) 400 micrograms per dose (200 doses)	‡1	5	..	20.13	21.22		Nitrolingual Pumpspray	SW

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ISOSORBIDE DINITRATE								
2588F *NP*	Sublingual tablet 5 mg	200	2	..	*14.56	15.65		Isordil Sublingual	QA
	ISOSORBIDE MONONITRATE								
1558B *NP*	Tablet 60 mg (sustained release)	30	5	..	11.92	13.01	a	Chem mart Isosorbide Mononitrate	CH
							a	Duride	AF
							a	GenRx Isosorbide Mononitrate	GX
							a	Imtrate 60 mg	GM
							a	Isomonit	SZ
							a	Monodur 60 mg	PM
							a	Terry White Chemists Isosorbide Mononitrate	TW
				B2.41	14.33	13.01	a	Imdur Durule	AP
8273K *NP*	Tablet 120 mg (sustained release)	30	5	..	19.45	20.54	a	Monodur 120 mg	PM
				B2.55	22.00	20.54	a	Imdur 120 mg	AP

Other vasodilators used in cardiac diseases

NICORANDIL

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8228C *NP*	Tablets 10 mg, 60	‡1	5	..	24.14	25.23		Ikorel	SW
8229D *NP*	Tablets 20 mg, 60	‡1	5	..	31.26	32.35		Ikorel	SW

PERHEXILINE MALEATE

Caution

Regular monitoring of drug serum levels is recommended.

Authority required (STREAMLINED)

1023

Angina not responding to other therapy.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1822X *NP*	Tablet 100 mg	100	5	..	62.62	35.40		Pexsig	QA

Antihypertensives

Antiadrenergic agents, centrally acting

Methyldopa

METHYLDOPA

1629R *NP*	Tablet 250 mg	100	5	..	13.30	14.39	a	Hydopa	AF
				B2.50	15.80	14.39	a	Aldomet	AS

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Imidazoline receptor agonists								
	CLONIDINE								
3141H *NP*	Tablet 150 micrograms	100	5	..	37.44	35.40		Catapres	BY
3145M *NP*	Tablet 100 micrograms	100	5	..	28.88	29.97		Catapres 100	BY
	MOXONIDINE **Restricted benefit** Hypertension in patients receiving concurrent antihypertensive therapy.								
9019Q *NP*	Tablet 200 micrograms	30	5	..	19.53	20.62		Physiotens	AB
9020R *NP*	Tablet 400 micrograms	30	5	..	28.78	29.87		Physiotens	AB
	Antiadrenergic agents, peripherally acting ***Alpha-adrenoceptor antagonists***								
	PRAZOSIN								
1478T *NP*	Tablet 5 mg (as hydrochloride)	100	5	..	20.57	21.66	[a]	APO-Prazosin	TX
							[a]	Chem mart Prazosin	CH
							[a]	Minipress	PF
							[a]	Terry White Chemists Prazosin	TW
1479W *NP*	Tablet 1 mg (as hydrochloride)	100	5	..	11.37	12.46	[a]	APO-Prazosin	TX
							[a]	Chem mart Prazosin	CH
							[a]	Minipress	PF
							[a]	Terry White Chemists Prazosin	TW
1480X *NP*	Tablet 2 mg (as hydrochloride)	100	5	..	14.30	15.39	[a]	APO-Prazosin	TX
							[a]	Chem mart Prazosin	CH
							[a]	Minipress	PF
							[a]	Terry White Chemists Prazosin	TW
	Arteriolar smooth muscle, agents acting on ***Hydrazinophthalazine derivatives***								
	HYDRALAZINE HYDROCHLORIDE								
1639G *NP*	Tablet 50 mg	200	2	..	*17.42	18.51		Alphapress 50	AF
1640H *NP*	Tablet 25 mg	200	2	..	*15.50	16.59		Alphapress 25	AF
	Pyrimidine derivatives								
	MINOXIDIL **Authority required (STREAMLINED)** ***2759*** Severe refractory hypertension. Treatment must be initiated by a consultant physician. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
2313R *NP*	Tablet 10 mg	100	5	..	52.83	35.40		Loniten	PF

Diuretics

Low-ceiling diuretics, thiazides

Thiazides, plain

HYDROCHLOROTHIAZIDE

1484D *NP*	Tablet 25 mg	100	1	..	21.24	22.33		Dithiazide	PL

Low-ceiling diuretics, excl. thiazides

Sulfonamides, plain

CHLORTHALIDONE

1585K *NP*	Tablet 25 mg	100	1	..	*17.58	18.67		Hygroton 25	LM

INDAPAMIDE HEMIHYDRATE

2436F *NP*	Tablet 2.5 mg	90	1	..	16.93	18.02	[a]	Chem mart Indapamide	CH
							[a]	Dapa-Tabs	AF
							[a]	GenRx Indapamide	GX
							[a]	Indapamide-GA	GM
							[a]	Indapamide Sandoz	SZ
							[a]	Insig	QA
							[a]	Terry White Chemists Indapamide	TW
				[B]2.43	19.36	18.02	[a]	Natrilix	SE
8532C *NP*	Tablet 1.5 mg (sustained release)	90	1	..	19.30	20.39		Natrilix SR	SE

High-ceiling diuretics

Sulfonamides, plain

FRUSEMIDE

2411X *NP*	Oral solution 10 mg per mL, 30 mL	‡1	3	..	17.06	18.15		Lasix	SW
2412Y *NP*	Tablet 40 mg	100	1	..	8.32	9.41	[a]	Chem mart Frusemide	CH
							[a]	Frusax	GN
							[a]	Frusemide-PS	FZ
							[a]	Frusemide Sandoz	SZ
							[a]	Frusid	GM
							[a]	GenRx Frusemide	GX
							[a]	Terry White Chemists Frusemide	TW
							[a]	Uremide	AF
								Urex	FM
				[B]2.00	10.32	9.41	[a]	Lasix	SW
2413B *NP*	Injection 20 mg in 2 mL	5	..	..	9.62	10.71	[a]	Frusemide-Claris	AE
							[a]	Frusemide Sandoz	SZ
							[a]	Lasix	SW
2414C *NP*	Tablet 20 mg	100	1	..	8.50	9.59	[a]	Chem mart Frusemide	CH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Frusemide-PS	FZ
							[a]	Frusid	GM
							[a]	GenRx Frusemide	GX
							[a]	Terry White Chemists Frusemide	TW
				..	*8.50	9.59		Urex-M	FM
				[B]1.60	*10.10	9.59	[a]	Lasix-M	SW
2415D *NP*	Tablet 500 mg	50	3	..	16.24	17.33		Urex-Forte	FM

Aryloxyacetic acid derivatives

ETHACRYNIC ACID
Restricted benefit
Patients hypersensitive to other oral diuretics.

8748K *NP*	Tablet 25 mg	200	1	..	*197.30	35.40		Edecrin	FK

Potassium-sparing agents
Aldosterone antagonists

EPLERENONE
Caution
Serum electrolytes should be checked regularly.

Authority required (STREAMLINED)
2637
Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.
The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient's medical records when PBS-subsidised treatment is initiated.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8879H *NP*	Tablet 25 mg	30	5	..	112.77	35.40		Inspra	PF
8880J *NP*	Tablet 50 mg	30	5	..	112.77	35.40		Inspra	PF

SPIRONOLACTONE
Caution
Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

Caution
Serum electrolytes should be checked regularly.

2339D *NP*	Tablet 25 mg	100	5	..	12.19	13.28	[a]	Spiractin 25	AF
				[B]1.75	13.94	13.28	[a]	Aldactone	PF
2340E *NP*	Tablet 100 mg	100	5	..	29.12	30.21	[a]	Spiractin 100	AF
				[B]2.40	31.52	30.21	[a]	Aldactone	PF

Diuretics and potassium-sparing agents in combination
Low-ceiling diuretics and potassium-sparing agents

HYDROCHLOROTHIAZIDE with AMILORIDE HYDROCHLORIDE
Caution
Serum electrolytes should be checked regularly.

1486F *NP*	Tablet 50 mg-5 mg	100	1	..	*13.50	14.59		Moduretic	AS

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	HYDROCHLOROTHIAZIDE with TRIAMTERENE								
	Caution								
	Serum electrolytes should be checked regularly.								
1280J	Tablet 25 mg-50 mg	100	1	..	12.89	13.98		Hydrene 25/50	AF
NP									

Peripheral vasodilators

Peripheral vasodilators

Other peripheral vasodilators

PHENOXYBENZAMINE HYDROCHLORIDE

Restricted benefit

Phaeochromocytoma;

Neurogenic urinary retention.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1166J	Capsules 10 mg, 30	3	5	..	*204.90	35.40		Dibenyline	GH
NP									
1862B	Capsule 10 mg	100	5	..	67.36	35.40		Dibenyline	GH
NP									
9286R	Capsules 10 mg, 100	‡1	5	..	1164.47	35.40		Dibenzyline	BZ
NP									

Beta blocking agents

Beta blocking agents

Beta blocking agents, non-selective

OXPRENOLOL HYDROCHLORIDE

2942W	Tablet 20 mg	100	5	..	27.88	28.97		Corbeton 20	AF
NP									
2961W	Tablet 40 mg	100	5	..	48.24	35.40		Corbeton 40	AF
NP									

PINDOLOL

3062E	Tablet 5 mg	100	5	..	33.36	34.45		Barbloc 5	AF
NP									
3065H	Tablet 15 mg	50	5	..	13.34	14.43	a	Barbloc 15	AF
NP									
				[B]2.57	15.91	14.43	a	Visken 15	NV

PROPRANOLOL HYDROCHLORIDE

2565B	Tablet 10 mg	100	5	..	10.19	11.28		Deralin 10	AF
NP									
				[B]3.14	13.33	11.28		Inderal	AP
2566C	Tablet 40 mg	100	5	..	10.56	11.65		Deralin 40	AF
NP									
				[B]3.14	13.70	11.65		Inderal	AP
2899N	Tablet 160 mg	50	5	..	11.01	12.10		Deralin 160	AF
NP									

SOTALOL HYDROCHLORIDE

Restricted benefit

Severe cardiac arrhythmias.

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2043M *NP*	Tablet 160 mg	60	5	..	20.02	21.11	a	Cardol	AF
							a	Chem mart Sotalol	CH
							a	GenRx Sotalol	GX
							a	Solavert	QA
							a	Sotalol Sandoz	SZ
							a	Terry White Chemists Sotalol	TW
				B3.40	23.42	21.11	a	Sotacor	FM
8398B *NP*	Tablet 80 mg	60	5	..	12.77	13.86	a	GenRx Sotalol	GX
							a	Solavert	QA
							a	Sotalol Sandoz	SZ
				B3.40	16.17	13.86	a	Sotacor	FM

Beta blocking agents, selective

ATENOLOL

1081X *NP*	Tablet 50 mg	30	5	..	8.81	9.90	a	APO-Atenolol	TX
							a	Atenolol-GA	GN
							a	Atenolol generichealth	GQ
							a	Atenolol-PS	FZ
							a	Atenolol Sandoz	SZ
							a	Chem mart Atenolol	CH
							a	Noten	AF
							a	Tensig	QA
							a	Terry White Chemists Atenolol	TW
				B2.21	11.02	9.90	a	Tenormin	AP

BISOPROLOL FUMARATE

Authority required (STREAMLINED)

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8604W *NP*	Tablet 2.5 mg	28	5	..	48.40	35.40	a	APO-Bisoprolol	TX
							a	Beprol 2.5	DO
							a	Bicard 2.5	QA
							a	Bicor	AL
							a	Biso 2.5	WQ
							a	Bisoprolol GH	GQ
							a	Bisoprolol Pfizer	FZ
							a	Bisoprolol Sandoz	SZ
							a	Bispro 2.5	AF
							a	Chem mart	CH

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Bisoprolol	
							a	Terry White Chemists Bisoprolol	TW
8605X *NP*	Tablet 5 mg	28	5	..	57.94	35.40	a	APO-Bisoprolol	TX
							a	Beprol 5	DO
							a	Bicard 5	QA
							a	Bicor	AL
							a	Biso 5	WQ
							a	Bisoprolol GH	GQ
							a	Bisoprolol Pfizer	FZ
							a	Bisoprolol Sandoz	SZ
							a	Bispro 5	AF
							a	Chem mart Bisoprolol	CH
							a	Terry White Chemists Bisoprolol	TW
8606Y *NP*	Tablet 10 mg	28	5	..	70.83	35.40	a	APO-Bisoprolol	TX
							a	Beprol 10	DO
							a	Bicard 10	QA
							a	Bicor	AL
							a	Biso 10	WQ
							a	Bisoprolol GH	GQ
							a	Bisoprolol Pfizer	FZ
							a	Bisoprolol Sandoz	SZ
							a	Bispro 10	AF
							a	Chem mart Bisoprolol	CH
							a	Terry White Chemists Bisoprolol	TW

METOPROLOL SUCCINATE

Authority required (STREAMLINED)

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8732N *NP*	Tablet 23.75 mg (controlled release)	15	..	..	21.04	22.13		Toprol-XL 23.75	AP
8733P *NP*	Tablet 47.5 mg (controlled release)	30	5	..	72.46	35.40		Toprol-XL 47.5	AP
8734Q *NP*	Tablet 95 mg (controlled release)	30	5	..	88.96	35.40		Toprol-XL 95	AP
8735R *NP*	Tablet 190 mg (controlled release)	30	5	..	109.60	35.40		Toprol-XL 190	AP

METOPROLOL TARTRATE

1324Q *NP*	Tablet 50 mg	100	5	..	9.82	10.91	a	Chem mart Metoprolol	CH
							a	GenRx Metoprolol	GX
							a	Metohexal	SZ
							a	Metrol 50	QA

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Minax 50	AF
							[a]	Terry White Chemists Metoprolol	TW
				[B]2.51	12.33	10.91	[a]	Betaloc	AP
				[B]2.52	12.34	10.91		Lopresor 50	NV
1325R *NP*	Tablet 100 mg	60	5	..	10.76	11.85	[a]	Chem mart Metoprolol	CH
							[a]	GenRx Metoprolol	GX
							[a]	Metohexal	SZ
							[a]	Metrol 100	QA
							[a]	Minax 100	AF
							[a]	Terry White Chemists Metoprolol	TW
				[B]2.50	13.26	11.85	[a]	Betaloc	AP
								Lopresor 100	NV

NEBIVOLOL
Authority required (STREAMLINED)
3234
Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9310B *NP*	Tablet 1.25 mg (as hydrochloride), 28	1	5	..	29.25	30.34		Nebilet	CS
9311C *NP*	Tablet 5 mg (as hydrochloride)	28	5	..	60.94	35.40		Nebilet	CS
9312D *NP*	Tablet 10 mg (as hydrochloride)	28	5	..	68.02	35.40		Nebilet	CS
9316H *NP*	Tablet 1.25 mg (as hydrochloride)	56	5	..	*50.62	35.40		Nebilet	CS

Alpha and beta blocking agents

CARVEDILOL
Authority required (STREAMLINED)
3234
Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated;

1735
Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8255L *NP*	Tablet 3.125 mg	30	..	..	12.81	13.90	[a]	APO-Carvedilol	TX
							[a]	Chem mart Carvedilol 3.125 mg	CH
							[a]	Dilatrend 3.125	RO
							[a]	GenRx Carvedilol	GX
							[a]	GN-Carvedilol	GM
							[a]	Terry White Chemists Carvedilol 3.125 mg	TW

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Vedilol 3.125	QA
							[a]	Volirop 3.125	DO
8256M *NP*	Tablet 6.25 mg	60	5	..	36.65	35.40	[a]	APO-Carvedilol	TX
							[a]	Carvedilol generichealth	GQ
							[a]	Carvedilol Sandoz	SZ
							[a]	Chem mart Carvedilol 6.25 mg	CH
							[a]	Dicarz	AF
							[a]	Dilatrend 6.25	RO
							[a]	GenRx Carvedilol	GX
							[a]	GN-Carvedilol	GM
							[a]	Terry White Chemists Carvedilol 6.25 mg	TW
							[a]	Vedilol 6.25	QA
							[a]	Volirop 6.25	DO
8257N *NP*	Tablet 12.5 mg	60	5	..	43.79	35.40	[a]	APO-Carvedilol	TX
							[a]	Carvedilol generichealth	GQ
							[a]	Carvedilol Sandoz	SZ
							[a]	Chem mart Carvedilol 12.5 mg	CH
							[a]	Dicarz	AF
							[a]	Dilatrend 12.5	RO
							[a]	GenRx Carvedilol	GX
							[a]	GN-Carvedilol	GM
							[a]	Terry White Chemists Carvedilol 12.5 mg	TW
							[a]	Vedilol 12.5	QA
							[a]	Volirop 12.5	DO
8258P *NP*	Tablet 25 mg	60	5	..	52.00	35.40	[a]	APO-Carvedilol	TX
							[a]	Carvedilol generichealth	GQ
							[a]	Carvedilol Sandoz	SZ
							[a]	Chem mart Carvedilol 25 mg	CH
							[a]	Dicarz	AF
							[a]	Dilatrend 25	RO
							[a]	GenRx Carvedilol	GX
							[a]	GN-Carvedilol	GM
							[a]	Terry White Chemists Carvedilol 25 mg	TW
							[a]	Vedilol 25	QA
							[a]	Volirop 25	DO
	LABETALOL HYDROCHLORIDE								
1566K *NP*	Tablet 100 mg	100	5	..	15.28	16.37	[a]	Presolol 100	AF
				[B]3.13	18.41	16.37	[a]	Trandate	QA

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
1567L	Tablet 200 mg	100	5	..	21.00	22.09	a	Presolol 200	AF
NP									
				B3.14	24.14	22.09	a	Trandate	QA

Calcium channel blockers

Selective calcium channel blockers with mainly vascular effects

Dihydropyridine derivatives

AMLODIPINE

Note

Pharmaceutical benefits that have the form amlodipine tablet 5 mg (as besylate) and pharmaceutical benefits that have the form amlodipine tablet 5 mg (as maleate) are equivalent for the purposes of substitution.

1343Q	Tablet 5 mg (as maleate)	30	5	..	11.46	12.55	a	Amlo 5	ZP
NP									
2751T	Tablet 5 mg (as besylate)	30	5	..	11.46	12.55	a	Amlodipine-DRLA	RZ
NP									
							a	Amlodipine-GA	GM
							a	Amlodipine generichealth	GQ
							a	Amlodipine Pfizer	FZ
							a	Amlodipine Sandoz	SZ
							a	APO-Amlodipine	TX
							a	Auro-Amlodipine 5	DO
							a	Chem mart Amlodipine	CH
							a	Nordip	AF
							a	Norvapine	GN
							a	Ozlodip	RA
							a	Pharmacor Amlodipine 5	CR
							a	Terry White Chemists Amlodipine	TW
				B1.92	13.38	12.55	a	Norvasc	PF

AMLODIPINE

Note

Pharmaceutical benefits that have the form amlodipine tablet 10 mg (as besylate) and pharmaceutical benefits that have the form amlodipine tablet 10 mg (as maleate) are equivalent for the purposes of substitution.

1345T	Tablet 10 mg (as maleate)	30	5	..	15.25	16.34	a	Amlo 10	ZP
NP									
2752W	Tablet 10 mg (as besylate)	30	5	..	15.25	16.34	a	Amlodipine-DRLA	RZ
NP									
							a	Amlodipine-GA	GM
							a	Amlodipine generichealth	GQ
							a	Amlodipine Pfizer	FZ
							a	Amlodipine Sandoz	SZ
							a	APO-Amlodipine	TX
							a	Auro-Amlodipine 10	DO
							a	Chem mart Amlodipine	CH
							a	Nordip	AF
							a	Norvapine	GN
							a	Ozlodip	RA
							a	Pharmacor	CR

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Amlodipine 10	
							a	Terry White Chemists Amlodipine	TW
				B2.80	18.05	16.34	a	Norvasc	PF
	FELODIPINE								
2361G *NP*	Tablet 2.5 mg (extended release)	30	5	..	11.61	12.70	a	Felodur ER 2.5 mg	AL
				B4.06	15.67	12.70	a	Plendil ER	AP
2366M *NP*	Tablet 5 mg (extended release)	30	5	..	13.87	14.96	a	Felodil XR 5	QA
							a	Felodur ER 5 mg	AL
				B4.07	17.94	14.96	a	Plendil ER	AP
2367N *NP*	Tablet 10 mg (extended release)	30	5	..	19.91	21.00	a	Felodil XR 10	QA
							a	Felodur ER 10 mg	AL
				B4.08	23.99	21.00	a	Plendil ER	AP
	LERCANIDIPINE HYDROCHLORIDE								
8534E *NP*	Tablet 10 mg	28	5	..	12.66	13.75	a	APO-Lercanidipine	TX
							a	Chem mart Lercanidipine	CH
							a	Lercadip	GM
							a	Lercan	QA
							a	Lercanidipine Sandoz	SZ
							a	Terry White Chemists Lercanidipine	TW
							a	Zircol	AF
				B2.66	15.32	13.75	a	Zanidip	AB
8679T *NP*	Tablet 20 mg	28	5	..	16.84	17.93	a	APO-Lercanidipine	TX
							a	Chem mart Lercanidipine	CH
							a	Lercadip	GM
							a	Lercan	QA
							a	Lercanidipine Sandoz	SZ
							a	Terry White Chemists Lercanidipine	TW
							a	Zircol	AF
				B2.64	19.48	17.93	a	Zanidip	AB
	NIFEDIPINE								
1694E *NP*	Tablet 10 mg	60	5	..	13.65	14.74	a	Adefin 10	AF
				B0.95	14.60	14.74	a	Adalat 10	BN
1695F *NP*	Tablet 20 mg	60	5	..	15.32	16.41	a	Adefin 20	AF
							a	GenRx Nifedipine	GX
							a	Nifehexal	SZ
				B1.76	17.08	16.41	a	Adalat 20	BN
1906H *NP*	Tablet 30 mg (controlled release)	30	5	..	16.43	17.52	a	Addos XR 30	QA
							a	Adefin XL 30	AF

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	APO-Nifedipine XR	TX
				[B]2.03	18.46	17.52	[a]	Adalat Oros 30	BN
1907J *NP*	Tablet 60 mg (controlled release)	30	5	..	18.98	20.07	[a]	Addos XR 60	QA
							[a]	Adefin XL 60	AF
							[a]	APO-Nifedipine XR	TX
				[B]2.24	21.22	20.07	[a]	Adalat Oros 60	BN
8610E *NP*	Tablet 20 mg (controlled release)	30	5	..	15.68	16.77		Adalat Oros 20mg	BN

Selective calcium channel blockers with direct cardiac effects

Phenylalkylamine derivatives

VERAPAMIL HYDROCHLORIDE

Caution

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

1060T *NP*	Injection 5 mg in 2 mL	5	..	..	12.38	13.47		Isoptin	AB
1241H *NP*	Tablet 240 mg (sustained release)	30	5	..	15.67	16.76	[a]	Cordilox SR	KN
				[B]2.15	17.82	16.76	[a]	Isoptin SR	AB
1248Q *NP*	Tablet 40 mg	100	5	..	11.26	12.35	[a]	Anpec 40	AF
				[B]0.73	11.99	12.35	[a]	Isoptin	AB
1250T *NP*	Tablet 80 mg	100	5	..	15.01	16.10	[a]	Anpec 80	AF
				[B]0.71	15.72	16.10	[a]	Isoptin	AB
1253Y *NP*	Tablet 160 mg	60	5	..	17.84	18.93		Isoptin	AB
1254B *NP*	Tablet 120 mg	100	5	..	18.86	19.95		Isoptin	AB
2206D *NP*	Capsule 160 mg (sustained release)	30	5	..	12.15	13.24		Veracaps SR	QA
2207E *NP*	Capsule 240 mg (sustained release)	30	5	..	15.75	16.84		Veracaps SR	QA
2208F *NP*	Tablet 180 mg (sustained release)	30	5	..	13.35	14.44	[a]	Cordilox 180 SR	KN
				[B]2.16	15.51	14.44	[a]	Isoptin 180 SR	AB

Benzothiazepine derivatives

DILTIAZEM HYDROCHLORIDE

Caution

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

1312C *NP*	Capsule 180 mg (controlled delivery)	30	5	..	15.07	16.16	[a]	Cardizem CD	SW
							[a]	Chem mart Diltiazem CD	CH
							[a]	Diltahexal CD	HX
							[a]	Diltiazem Sandoz CD	SZ
							[a]	GenRx Diltiazem CD	GX
							[a]	Terry White Chemists Diltiazem CD	TW
							[a]	Vasocardol CD	AV
1313D *NP*	Capsule 240 mg (controlled delivery)	30	5	..	18.10	19.19	[a]	Cardizem CD	SW
							[a]	Chem mart Diltiazem CD	CH
							[a]	Diltahexal CD	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	GenRx Diltiazem CD	GX
							[a]	Terry White Chemists Diltiazem CD	TW
							[a]	Vasocardol CD	AV
1335G *NP*	Tablet 60 mg	90	5	..	14.22	15.31	[a]	Cardizem	SW
							[a]	Chem mart Diltiazem	CH
							[a]	Coras	AF
							[a]	Diltiazem Sandoz	SZ
							[a]	Dilzem 60 mg	GM
							[a]	GenRx Diltiazem	GX
							[a]	Terry White Chemists Diltiazem	TW
							[a]	Vasocardol	AV
8480H *NP*	Capsule 360 mg (controlled delivery)	30	5	..	21.74	22.83	[a]	Cardizem CD	SW
							[a]	Diltahexal CD	SZ
							[a]	Vasocardol CD	AV

Agents acting on the renin-angiotensin system

ACE inhibitors, plain

ACE inhibitors, plain

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

CAPTOPRIL

1147J *NP*	Tablet 12.5 mg	90	5	..	14.67	15.76	[a]	Captopril Sandoz	SZ
							[a]	GenRx Captopril	GX
							[a]	Zedace	AF
1148K *NP*	Tablet 25 mg	90	5	..	18.36	19.45	[a]	Captopril Sandoz	SZ
							[a]	GenRx Captopril	GX
							[a]	Zedace	AF
				[B]4.03	22.39	19.45	[a]	Capoten	QA
1149L *NP*	Tablet 50 mg	90	5	..	29.97	31.06	[a]	Captopril Sandoz	SZ
							[a]	GenRx Captopril	GX
							[a]	Zedace	AF
				[B]4.03	34.00	31.06	[a]	Capoten	QA

CAPTOPRIL

Restricted benefit

For patients unable to take a solid dose form of an ACE inhibitor.

8760C *NP*	Oral solution 5 mg per mL, 95 mL	‡1	5	..	111.82	35.40		Capoten	QA

ENALAPRIL

1368B *NP*	Tablet containing enalapril maleate 10 mg	30	5	..	13.76	14.85	[a]	Acetec	AL
							[a]	Auspril	QA
							[a]	Chem mart Enalapril	CH

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Enalapril-GA	GM
							[a]	Enalapril generichealth	GQ
							[a]	Enalapril Sandoz	SZ
							[a]	GenRx Enalapril	GX
							[a]	Terry White Chemists Enalapril	TW
				[B]3.49	17.25	14.85	[a]	Renitec	MK
1369C *NP*	Tablet containing enalapril maleate 20 mg	30	5	..	15.76	16.85	[a]	Acetec	AL
							[a]	Auspril	QA
							[a]	Chem mart Enalapril	CH
							[a]	Enalapril-GA	GM
							[a]	Enalapril generichealth	GQ
							[a]	Enalapril Sandoz	SZ
							[a]	GenRx Enalapril	GX
							[a]	Terry White Chemists Enalapril	TW
				[B]3.49	19.25	16.85	[a]	Renitec 20	MK
1370D *NP*	Tablet containing enalapril maleate 5 mg	30	5	..	10.88	11.97	[a]	Acetec	AL
							[a]	Auspril	QA
							[a]	Chem mart Enalapril	CH
							[a]	Enalapril-GA	GM
							[a]	Enalapril generichealth	GQ
							[a]	Enalapril Sandoz	SZ
							[a]	GenRx Enalapril	GX
							[a]	Terry White Chemists Enalapril	TW
				[B]3.49	14.37	11.97	[a]	Renitec M	MK
	FOSINOPRIL SODIUM								
1182F *NP*	Tablet 10 mg	30	5	..	15.19	16.28	[a]	Fosipril 10	QA
							[a]	GenRx Fosinopril	GX
							[a]	Monace 10	AF
							[a]	Monopril	BQ
1183G *NP*	Tablet 20 mg	30	5	..	19.56	20.65	[a]	Fosipril 20	QA
							[a]	GenRx Fosinopril	GX
							[a]	Monace 20	AF
							[a]	Monopril	BQ
	LISINOPRIL								
2456G *NP*	Tablet 5 mg	30	5	..	11.88	12.97	[a]	APO-Lisinopril	TX
							[a]	Chem mart Lisinopril	CH
							[a]	Fibsol 5	QA
							[a]	GenRx Lisinopril	GX
							[a]	Lisinopril 5	CR

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Lisinopril-DRLA	RZ
							[a]	Lisinopril-GA	GN
							[a]	Lisinopril generichealth	GQ
							[a]	Lisinopril-PS	FZ
							[a]	Lisinopril Ranbaxy	RA
							[a]	Lisinopril Sandoz	SZ
							[a]	Lisodur	AF
							[a]	Terry White Chemists Lisinopril	TW
				[B]1.47	13.35	12.97	[a]	Zestril	AP
				[B]2.96	14.84	12.97	[a]	Prinivil 5	MK
2457H *NP*	Tablet 10 mg	30	5	..	14.62	15.71	[a]	APO-Lisinopril	TX
							[a]	Chem mart Lisinopril	CH
							[a]	Fibsol 10	QA
							[a]	GenRx Lisinopril	GX
							[a]	Lisinopril 10	CR
							[a]	Lisinopril-DRLA	RZ
							[a]	Lisinopril-GA	GN
							[a]	Lisinopril generichealth	GQ
							[a]	Lisinopril-PS	FZ
							[a]	Lisinopril Ranbaxy	RA
							[a]	Lisinopril Sandoz	SZ
							[a]	Lisodur	AF
							[a]	Terry White Chemists Lisinopril	TW
				[B]1.47	16.09	15.71	[a]	Zestril	AP
				[B]2.94	17.56	15.71	[a]	Prinivil 10	MK
2458J *NP*	Tablet 20 mg	30	5	..	16.75	17.84	[a]	APO-Lisinopril	TX
							[a]	Chem mart Lisinopril	CH
							[a]	Fibsol 20	QA
							[a]	GenRx Lisinopril	GX
							[a]	Lisinopril 20	CR
							[a]	Lisinopril-DRLA	RZ
							[a]	Lisinopril-GA	GN
							[a]	Lisinopril generichealth	GQ
							[a]	Lisinopril-PS	FZ
							[a]	Lisinopril Ranbaxy	RA
							[a]	Lisinopril Sandoz	SZ
							[a]	Lisodur	AF
							[a]	Terry White Chemists Lisinopril	TW
				[B]1.47	18.22	17.84	[a]	Zestril	AP
				[B]2.94	19.69	17.84	[a]	Prinivil 20	MK

PERINDOPRIL

Note

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Pharmaceutical benefits that have the form perindopril erbumine tablet 2 mg and pharmaceutical benefits that have the form perindopril arginine tablet 2.5 mg are equivalent for the purposes of substitution.								
3050M *NP*	Tablet containing 2 mg perindopril erbumine	30	5	..	11.38	12.47	a	APO-Perindopril	TX
							a	Chem mart Perindopril	CH
							a	GenRx Perindopril	GX
							a	Idaprex 2	SZ
							a	Indopril 2	QA
							a	Ozapace	RA
							a	Perindo	AF
							a	Perindopril 2	CR
							a	Perindopril-DP	GN
							a	Perindopril-GA	GM
							a	Perindopril generichealth	GQ
							a	Terry White Chemists Perindopril	TW
9006B *NP*	Tablet containing 2.5 mg perindopril arginine	30	5	..	11.38	12.47	a	Coversyl 2.5mg	SE

PERINDOPRIL

Note

Pharmaceutical benefits that have the form perindopril erbumine tablet 4 mg and pharmaceutical benefits that have the form perindopril arginine tablet 5 mg are equivalent for the purposes of substitution.

3051N *NP*	Tablet containing 4 mg perindopril erbumine	30	5	..	15.69	16.78	a	APO-Perindopril	TX
							a	Chem mart Perindopril	CH
							a	GenRx Perindopril	GX
							a	Idaprex 4	SZ
							a	Indopril 4	QA
							a	Ozapace	RA
							a	Perindo	AF
							a	Perindopril 4	CR
							a	Perindopril-DP	GN
							a	Perindopril-GA	GM
							a	Perindopril generichealth	GQ
							a	Terry White Chemists Perindopril	TW
9007C *NP*	Tablet containing 5 mg perindopril arginine	30	5	..	15.69	16.78	a	Coversyl 5mg	SE

PERINDOPRIL

Note

Pharmaceutical benefits that have the form perindopril erbumine tablet 8 mg and pharmaceutical benefits that have the form perindopril arginine tablet 10 mg are equivalent for the purposes of substitution.

8704D *NP*	Tablet containing 8 mg perindopril erbumine	30	5	..	20.62	21.71	a	APO-Perindopril	TX
							a	Chem mart Perindopril	CH
							a	GenRx Perindopril	GX
							a	Idaprex 8	SZ

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Indopril 8	QA
							[a]	Ozapace	RA
							[a]	Perindo	AF
							[a]	Perindopril 8	CR
							[a]	Perindopril-DP	GN
							[a]	Perindopril-GA	GM
							[a]	Perindopril generichealth	GQ
							[a]	Terry White Chemists Perindopril	TW
9008D *NP*	Tablet containing 10 mg perindopril arginine	30	5	..	20.62	21.71	[a]	Coversyl 10mg	SE
	QUINAPRIL								
1968N *NP*	Tablet 5 mg (as hydrochloride)	30	5	..	11.84	12.93	[a]	Acquin 5	QA
							[a]	Acquin Aspen 5	AS
							[a]	APO-Quinapril	TX
							[a]	Aquinafil	GN
							[a]	Pharmacor Quinapril 5	CR
							[a]	Qpril 5	AF
							[a]	Quinapril generichealth	GQ
							[a]	Quinapril Pfizer	FZ
							[a]	Quinapril Sandoz	SZ
				[B]0.34	12.18	12.93	[a]	Accupril	PF
1969P *NP*	Tablet 10 mg (as hydrochloride)	30	5	..	14.15	15.24	[a]	Acquin 10	QA
							[a]	Acquin Aspen 10	AS
							[a]	APO-Quinapril	TX
							[a]	Aquinafil	GN
							[a]	Pharmacor Quinapril 10	CR
							[a]	Qpril 10	AF
							[a]	Quinapril generichealth	GQ
							[a]	Quinapril Pfizer	FZ
				[B]0.47	14.62	15.24	[a]	Accupril	PF
1970Q *NP*	Tablet 20 mg (as hydrochloride)	30	5	..	15.99	17.08	[a]	Acquin 20	QA
							[a]	Acquin Aspen 20	AS
							[a]	APO-Quinapril	TX
							[a]	Aquinafil	GN
							[a]	Pharmacor Quinapril 20	CR
							[a]	Qpril 20	AF
							[a]	Quinapril-GA	GM
							[a]	Quinapril generichealth	GQ
							[a]	Quinapril Pfizer	FZ
							[a]	Quinapril Sandoz	SZ
				[B]0.72	16.71	17.08	[a]	Accupril	PF

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	RAMIPRIL								
	Note								
	Pharmaceutical benefits that have the form ramipril tablet 1.25 mg and pharmaceutical benefits that have the form ramipril capsule 1.25 mg are equivalent for the purposes of substitution.								
1944H *NP*	Tablet 1.25 mg	30	5	..	9.50	10.59	a	APO-Ramipril	TX
							a	Chem mart Ramipril	CH
							a	Prilace 1.25	QA
							a	Ramace 1.25 mg	AV
							a	Ramipril Sandoz	SZ
							a	Ramipril Tabs Pfizer	FZ
							a	Ramipril Winthrop	WA
							a	Terry White Chemists Ramipril	TW
							a	Tritace 1.25 mg	SW
							a	Tryzan Tabs 1.25	AF
							a	Vascalace 1.25	DO
9120B *NP*	Capsule 1.25 mg	30	5	..	9.50	10.59	a	Pharmacor Ramipril 1.25	CR
							a	Ramipril-GA	GM
							a	Ramipril generichealth	GQ
							a	Tryzan Caps 1.25	AF
	RAMIPRIL								
	Note								
	Pharmaceutical benefits that have the form ramipril tablet 2.5 mg and pharmaceutical benefits that have the form ramipril capsule 2.5 mg are equivalent for the purposes of substitution.								
1945J *NP*	Tablet 2.5 mg	30	5	..	10.92	12.01	a	APO-Ramipril	TX
							a	Chem mart Ramipril	CH
							a	Prilace 2.5	QA
							a	Ramace 2.5 mg	AV
							a	Ramipril Sandoz	SZ
							a	Ramipril Tabs Pfizer	FZ
							a	Ramipril Winthrop	WA
							a	Terry White Chemists Ramipril	TW
							a	Tritace 2.5 mg	SW
							a	Tryzan Tabs 2.5	AF
							a	Vascalace 2.5	DO
9121C *NP*	Capsule 2.5 mg	30	5	..	10.92	12.01	a	Pharmacor Ramipril 2.5	CR
							a	Ramipril-GA	GM
							a	Ramipril generichealth	GQ
							a	Tryzan Caps 2.5	AF
	RAMIPRIL								
	Note								
	Pharmaceutical benefits that have the form ramipril tablet 5 mg and pharmaceutical benefits that have the form ramipril capsule 5 mg are equivalent for the purposes of substitution.								

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
1946K *NP*	Tablet 5 mg	30	5	..	12.07	13.16	a	APO-Ramipril	TX
							a	Chem mart Ramipril	CH
							a	Prilace 5	QA
							a	Ramace 5 mg	AV
							a	Ramipril Sandoz	SZ
							a	Ramipril Tabs Pfizer	FZ
							a	Ramipril Winthrop	WA
							a	Terry White Chemists Ramipril	TW
							a	Tritace 5 mg	SW
							a	Tryzan Tabs 5	AF
							a	Vascalace 5	DO
9122D *NP*	Capsule 5 mg	30	5	..	12.07	13.16	a	Pharmacor Ramipril 5	CR
							a	Ramipril-GA	GM
							a	Ramipril generichealth	GQ
							a	Tryzan Caps 5	AF

RAMIPRIL

Note

Pharmaceutical benefits that have the form ramipril tablet 10 mg and pharmaceutical benefits that have the form ramipril capsule 10 mg are equivalent for the purposes of substitution.

1316G *NP*	Tablet 10 mg	30	5	..	16.40	17.49	a	APO-Ramipril	TX
							a	Chem mart Ramipril	CH
							a	Ramipril Sandoz	SZ
							a	Ramipril Tabs Pfizer	FZ
							a	Terry White Chemists Ramipril	TW
							a	Tritace	SW
							a	Tryzan Tabs 10	AF
							a	Vascalace 10	DO
8470T *NP*	Capsule 10 mg	30	5	..	16.40	17.49	a	APO-Ramipril	TX
							a	Chem mart Ramipril	CH
							a	GenRx Ramipril	GX
							a	Pharmacor Ramipril 10	CR
							a	Prilace 10	QA
							a	Ramace 10 mg	AV
							a	Ramipril-GA	GM
							a	Ramipril generichealth	GQ
							a	Ramipril-PS	FZ
							a	Ramipril Sandoz	SZ
							a	Ramipril Winthrop	WA
							a	Terry White Chemists Ramipril	TW
							a	Tritace 10 mg	SW

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Tryzan Caps 10	AF
	RAMIPRIL								
8668F *NP*	Pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg	‡1	..	..	15.68	16.77		Tritace Titration Pack	SW
	TRANDOLAPRIL								
2791X *NP*	Capsule 500 micrograms	28	5	..	8.58	9.67	[a]	APO-Trandolapril	TX
							[a]	Dolapril 0.5	QA
							[a]	Tranalpha	AF
							[a]	Trandolapril-DP	GN
							[a]	Trandolapril generichealth	GQ
				[B]1.39	9.97	9.67	[a]	Gopten	AB
2792Y *NP*	Capsule 1 mg	28	5	..	12.15	13.24	[a]	APO-Trandolapril	TX
							[a]	Dolapril 1	QA
							[a]	Tranalpha	AF
							[a]	Trandolapril-DP	GN
							[a]	Trandolapril generichealth	GQ
				[B]1.41	13.56	13.24	[a]	Gopten	AB
2793B *NP*	Capsule 2 mg	28	5	..	13.33	14.42	[a]	APO-Trandolapril	TX
							[a]	Dolapril 2	QA
							[a]	Tranalpha	AF
							[a]	Trandolapril-DP	GN
							[a]	Trandolapril generichealth	GQ
				[B]1.40	14.73	14.42	[a]	Gopten	AB
8758Y *NP*	Capsule 4 mg	28	5	..	19.39	20.48	[a]	APO-Trandolapril	TX
							[a]	Dolapril 4	QA
							[a]	Tranalpha	AF
							[a]	Trandolapril-DP	GN
							[a]	Trandolapril generichealth	GQ
				[B]1.42	20.81	20.48	[a]	Gopten	AB

ACE inhibitors, combinations

ACE inhibitors and diuretics

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

ENALAPRIL MALEATE with HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.

8477E *NP*	Tablet 20 mg-6 mg	30	5	..	27.60	28.69	[a]	Enalapril/HCT Sandoz	SZ
							[a]	Renitec Plus 20/6	MK

FOSINOPRIL SODIUM with HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.

8400D	Tablet 10 mg-12.5 mg	30	5	..	21.32	22.41	[a]	APO-Fosinopril	TX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP								HCTZ 10/12.5	
							[a]	Fosinopril/HCTZ-GA 10/12.5	GM
							[a]	Hyforil	RA
							[a]	Monoplus 10/12.5	BQ
8401E *NP*	Tablet 20 mg-12.5 mg	30	5	..	28.30	29.39	[a]	APO-Fosinopril HCTZ 20/12.5	TX
							[a]	Fosetic 20/12.5	ZP
							[a]	Fosinopril/HCTZ-GA 20/12.5	GM
							[a]	Hyforil	RA
							[a]	Monoplus 20/12.5	BQ
	PERINDOPRIL with INDAPAMIDE HEMIHYDRATE								
2190G *NP*	Tablet containing 2.5 mg perindopril arginine-0.625 mg indapamide hemihydrate	30	5	..	16.13	17.22		Coversyl Plus LD 2.5mg/0.625mg	SE

PERINDOPRIL with INDAPAMIDE HEMIHYDRATE

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.

Note

Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

2845R *NP*	Tablet containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate	30	5	..	28.22	29.31	[a]	Coversyl Plus 5mg/1.25mg	SE
8449Q *NP*	Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate	30	5	..	28.22	29.31	[a]	Chem mart Perindopril/ Indapamide 4/1.25	CH
							[a]	GenRx Perindopril/ Indapamide 4/1.25	GX
							[a]	Idaprex Combi 4/1.25	SZ
							[a]	Indopril Combi 4/1.25	QA
							[a]	Perindo Combi 4/1.25	AF
							[a]	Perindopril/ Indapamide GH 4/1.25	GQ
							[a]	Terry White Chemists Perindopril/ Indapamide 4/1.25	TW

QUINAPRIL HYDROCHLORIDE with HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.

8589C *NP*	Tablet 10 mg (base)-12.5 mg	30	5	..	16.37	17.46		Accuretic 10/12.5mg	PF
8590D *NP*	Tablet 20 mg (base)-12.5 mg	30	5	..	18.21	19.30		Accuretic 20/12.5mg	PF

ACE inhibitors and calcium channel blockers

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	LERCANIDIPINE HYDROCHLORIDE with ENALAPRIL MALEATE								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.								
9144G *NP*	Tablet 10 mg-10 mg	28	5	..	19.51	20.60		Zan-Extra 10/10	AB
9145H *NP*	Tablet 10 mg-20 mg	28	5	..	21.38	22.47		Zan-Extra 10/20	AB
	PERINDOPRIL with AMLODIPINE								
	Note								
	Treatment should not be initiated with this combination.								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination;								
	Stable coronary heart disease in a patient who is stabilised on treatment with perindopril and amlodipine at the same doses.								
9346X *NP*	Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besylate)	30	5	..	27.11	28.20	[a]	Coveram	SE
							[a]	Reaptan 5/5	RX
9347Y *NP*	Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besylate)	30	5	..	34.45	35.40	[a]	Coveram	SE
							[a]	Reaptan 5/10	RX
9348B *NP*	Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besylate)	30	5	..	32.94	34.03	[a]	Coveram	SE
							[a]	Reaptan 10/5	RX
9349C *NP*	Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besylate)	30	5	..	40.26	35.40	[a]	Coveram	SE
							[a]	Reaptan 10/10	RX
	RAMIPRIL with FELODIPINE								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.								
2626F *NP*	Tablet 2.5 mg-2.5 mg (modified release)	30	5	..	16.10	17.19		Triasyn 2.5/2.5	SW
2629J *NP*	Tablet 5 mg-5 mg (modified release)	30	5	..	19.52	20.61		Triasyn 5.0/5.0	SW
	TRANDOLAPRIL with VERAPAMIL HYDROCHLORIDE								
	Caution								
	The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.								
2857J *NP*	Tablet 4 mg-240 mg (sustained release)	28	5	..	28.02	29.11		Tarka 4/240	AB
9387C *NP*	Tablet 2 mg-180 mg (sustained release)	28	5	..	19.81	20.90		Tarka 2/180	AB

Angiotensin II antagonists, plain
Angiotensin II antagonists, plain

	CANDESARTAN CILEXETIL								
8295N *NP*	Tablet 4 mg	30	5	..	9.10	10.19		Atacand	AP
8296P *NP*	Tablet 8 mg	30	5	[T]2.95	17.12	15.26		Atacand	AP
8297Q *NP*	Tablet 16 mg	30	5	[T]3.26	32.17	30.00		Atacand	AP
8889W *NP*	Tablet 32 mg	30	5	[T]2.87	39.56	35.40		Atacand	AP

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	CANDESARTAN CILEXETIL								
	Authority required								
	Adverse effects occurring with all of the base-priced drugs;								
	Drug interactions occurring with all of the base-priced drugs;								
	Drug interactions expected to occur with all of the base-priced drugs;								
	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.								
8997M *NP*	Tablet 8 mg	30	5	..	17.12	18.21		Atacand	AP
8998N *NP*	Tablet 16 mg	30	5	..	32.17	33.26		Atacand	AP
8999P *NP*	Tablet 32 mg	30	5	..	39.56	35.40		Atacand	AP
	EPROSARTAN MESYLATE								
8397Y *NP*	Tablet 400 mg (base)	56	5	T3.48	*26.86	24.47		Teveten	AB
8447N *NP*	Tablet 600 mg (base)	28	5	T2.00	29.63	28.72		Teveten	AB
	EPROSARTAN MESYLATE								
	Authority required								
	Adverse effects occurring with all of the base-priced drugs;								
	Drug interactions occurring with all of the base-priced drugs;								
	Drug interactions expected to occur with all of the base-priced drugs;								
	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.								
5491B *NP*	Tablet 600 mg (base)	28	5	..	29.63	30.72		Teveten	AB
8951D *NP*	Tablet 400 mg (base)	56	5	..	*26.86	27.95		Teveten	AB
	IRBESARTAN								
8246B *NP*	Tablet 75 mg	30	5	..	14.46	15.55	a	Avapro	BQ
							a	Karvea	SW
8247C *NP*	Tablet 150 mg	30	5	..	17.90	18.99	a	Avapro	BQ
							a	Karvea	SW
8248D *NP*	Tablet 300 mg	30	5	..	29.36	30.45	a	Avapro	BQ
							a	Karvea	SW
	LOSARTAN								
5452Y *NP*	Tablet containing losartan potassium 25 mg	30	5	..	13.92	15.01		Cozavan	AF
8203R *NP*	Tablet containing losartan potassium 50 mg	60	5	..	*27.84	28.93		Cozavan	AF
	OLMESARTAN MEDOXOMIL								
2147B *NP*	Tablet 20 mg	30	5	T1.00	18.35	18.44		Olmetec	MK
2148C *NP*	Tablet 40 mg	30	5	T1.00	30.62	30.71		Olmetec	MK
	OLMESARTAN MEDOXOMIL								
	Authority required								
	Adverse effects occurring with all of the base-priced drugs;								

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Drug interactions occurring with all of the base-priced drugs;							
	Drug interactions expected to occur with all of the base-priced drugs;							
	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.							
5492C *NP*	Tablet 20 mg	30	5	..	18.35	19.44	Olmetec	MK
5493D *NP*	Tablet 40 mg	30	5	..	30.62	31.71	Olmetec	MK
	TELMISARTAN							
8355R *NP*	Tablet 40 mg	28	5	T2.00	16.17	15.26	Micardis	BY
8356T *NP*	Tablet 80 mg	28	5	T1.99	30.90	30.00	Micardis	BY
	TELMISARTAN							
	Authority required							
	Adverse effects occurring with all of the base-priced drugs;							
	Drug interactions occurring with all of the base-priced drugs;							
	Drug interactions expected to occur with all of the base-priced drugs;							
	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.							
5494E *NP*	Tablet 40 mg	28	5	..	16.17	17.26	Micardis	BY
5495F *NP*	Tablet 80 mg	28	5	..	30.90	31.99	Micardis	BY
	VALSARTAN							
9368C *NP*	Tablet 40 mg	28	..	..	15.42	16.51	Diovan	NV
9369D *NP*	Tablet 80 mg	28	5	..	19.40	20.49	Diovan	NV
9370E *NP*	Tablet 160 mg	28	5	..	23.05	24.14	Diovan	NV
	VALSARTAN							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.							
9371F *NP*	Tablet 320 mg	28	5	..	27.63	28.72	Diovan	NV

Angiotensin II antagonists, combinations
Angiotensin II antagonists and diuretics

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	CANDESARTAN CILEXETIL with HYDROCHLOROTHIAZIDE							
	Restricted benefit							
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.							
8504N *NP*	Tablet 16 mg-12.5 mg	30	5	..	31.13	32.22	Atacand Plus 16/12.5	AP
9314F *NP*	Tablet 32 mg-12.5 mg	30	5	..	38.91	35.40	Atacand Plus 32/12.5	AP
9315G *NP*	Tablet 32 mg-25 mg	30	5	..	41.11	35.40	Atacand Plus 32/25	AP
	EPROSARTAN MESYLATE with HYDROCHLOROTHIAZIDE							
	Restricted benefit							
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.							
8624X *NP*	Tablet 600 mg (base)-12.5 mg	28	5	..	29.70	30.79	Teveten Plus 600/12.5	AB

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	IRBESARTAN with HYDROCHLOROTHIAZIDE								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.								
2136K	Tablet 300 mg-25 mg	30	5	..	33.81	34.90	a	Avapro HCT 300/25	BQ
NP							a	Karvezide 300/25	SW
8404H	Tablet 150 mg-12.5 mg	30	5	..	20.12	21.21	a	Avapro HCT 150/12.5	BQ
NP							a	Karvezide 150/12.5	SW
8405J	Tablet 300 mg-12.5 mg	30	5	..	31.58	32.67	a	Avapro HCT 300/12.5	BQ
NP							a	Karvezide 300/12.5	SW
	OLMESARTAN MEDOXOMIL with HYDROCHLOROTHIAZIDE								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.								
2161R	Tablet 20 mg-12.5 mg	30	5	..	19.56	20.65		Olmetec Plus	MK
NP									
2166B	Tablet 40 mg-12.5 mg	30	5	..	31.84	32.93		Olmetec Plus	MK
NP									
2170F	Tablet 40 mg-25 mg	30	5	..	34.07	35.16		Olmetec Plus	MK
NP									
	TELMISARTAN with HYDROCHLOROTHIAZIDE								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.								
8622T	Tablet 40 mg-12.5 mg	28	5	..	16.24	17.33		Micardis Plus 40/12.5 mg	BY
NP									
8623W	Tablet 80 mg-12.5 mg	28	5	..	30.98	32.07		Micardis Plus 80/12.5 mg	BY
NP									
9381R	Tablet 80 mg-25 mg	28	5	..	33.07	34.16		Micardis Plus 80/25 mg	BY
NP									
	VALSARTAN with HYDROCHLOROTHIAZIDE								
	Restricted benefit								
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.								
9372G	Tablet 80 mg-12.5 mg	28	5	..	21.47	22.56		Co-Diovan 80/12.5	NV
NP									
9373H	Tablet 160 mg-12.5 mg	28	5	..	25.12	26.21		Co-Diovan 160/12.5	NV
NP									
9374J	Tablet 160 mg-25 mg	28	5	..	27.20	28.29		Co-Diovan 160/25	NV
NP									

VALSARTAN with HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.

Note

No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

9481B	Tablet 320 mg-12.5 mg	28	5	..	29.70	30.79		Co-Diovan 320/12.5	NV
NP									
9482C	Tablet 320 mg-25 mg	28	5	..	31.78	32.87		Co-Diovan 320/25	NV
NP									

Angiotensin II antagonists and calcium channel blockers

AMLODIPINE with VALSARTAN

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.

5459H	Tablet 5 mg (as besylate)-320 mg	28	5	..	32.33	33.42		Exforge 5/320	NV

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
NP								
5460J	Tablet 10 mg (as besylate)-320 mg	28	5	..	35.87	35.40	Exforge 10/320	NV
NP								
9375K	Tablet 5 mg (as besylate)-80 mg	28	5	..	24.11	25.20	Exforge 5/80	NV
NP								
9376L	Tablet 5 mg (as besylate)-160 mg	28	5	..	27.75	28.84	Exforge 5/160	NV
NP								
9377M	Tablet 10 mg (as besylate)-160 mg	28	5	..	31.29	32.38	Exforge 10/160	NV
NP								
	OLMESARTAN with AMLODIPINE							
	Restricted benefit							
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.							
5292M	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besylate)	30	5	..	22.38	23.47	Sevikar 20/5	MK
5293N	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besylate)	30	5	..	34.65	35.40	Sevikar 40/5	MK
5294P	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besylate)	30	5	..	38.45	35.40	Sevikar 40/10	MK
	TELMISARTAN with AMLODIPINE							
	Restricted benefit							
	Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.							
8978M	Tablet 40 mg-5 mg (as besylate)	28	5	..	18.87	19.96	Twynsta	BY
NP								
8979N	Tablet 40 mg-10 mg (as besylate)	28	5	..	22.42	23.51	Twynsta	BY
NP								
8980P	Tablet 80 mg-5 mg (as besylate)	28	5	..	33.62	34.71	Twynsta	BY
NP								
8981Q	Tablet 80 mg-10 mg (as besylate)	28	5	..	37.16	35.40	Twynsta	BY
NP								

Angiotensin II antagonists, other combinations

	AMLODIPINE with VALSARTAN and HYDROCHLOROTHIAZIDE							
	Restricted benefit							
	Hypertension in a patient who is not adequately controlled with any two of the drugs in the combination.							
5285E	Tablet 5 mg (as besylate)-160 mg-12.5 mg	28	5	..	29.82	30.91	Exforge HCT 5/160/12.5	NV
NP								
5286F	Tablet 5 mg (as besylate)-160 mg-25 mg	28	5	..	31.90	32.99	Exforge HCT 5/160/25	NV
NP								
5287G	Tablet 10 mg (as besylate)-160 mg-12.5 mg	28	5	..	33.36	34.45	Exforge HCT 10/160/12.5	NV
NP								
5288H	Tablet 10 mg (as besylate)-160 mg-25 mg	28	5	..	35.45	35.40	Exforge HCT 10/160/25	NV
NP								
5289J	Tablet 10 mg (as besylate)-320 mg-25 mg	28	5	..	40.02	35.40	Exforge HCT 10/320/25	NV
NP								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

GENERAL STATEMENT FOR LIPID-LOWERING DRUGS PRESCRIBED AS PHARMACEUTICAL BENEFITS

Use the following criteria to determine patient eligibility for subsidisation under the PBS for the following drugs:

- atorvastatin calcium
- fluvastatin sodium
- pravastatin sodium
- rosuvastatin calcium
- simvastatin
- fenofibrate
- gemfibrozil

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use is in accordance with the registered indications which differ between agents in this class - refer to the current Product Information for details. Note also that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.

Patients in very high risk categories (see below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

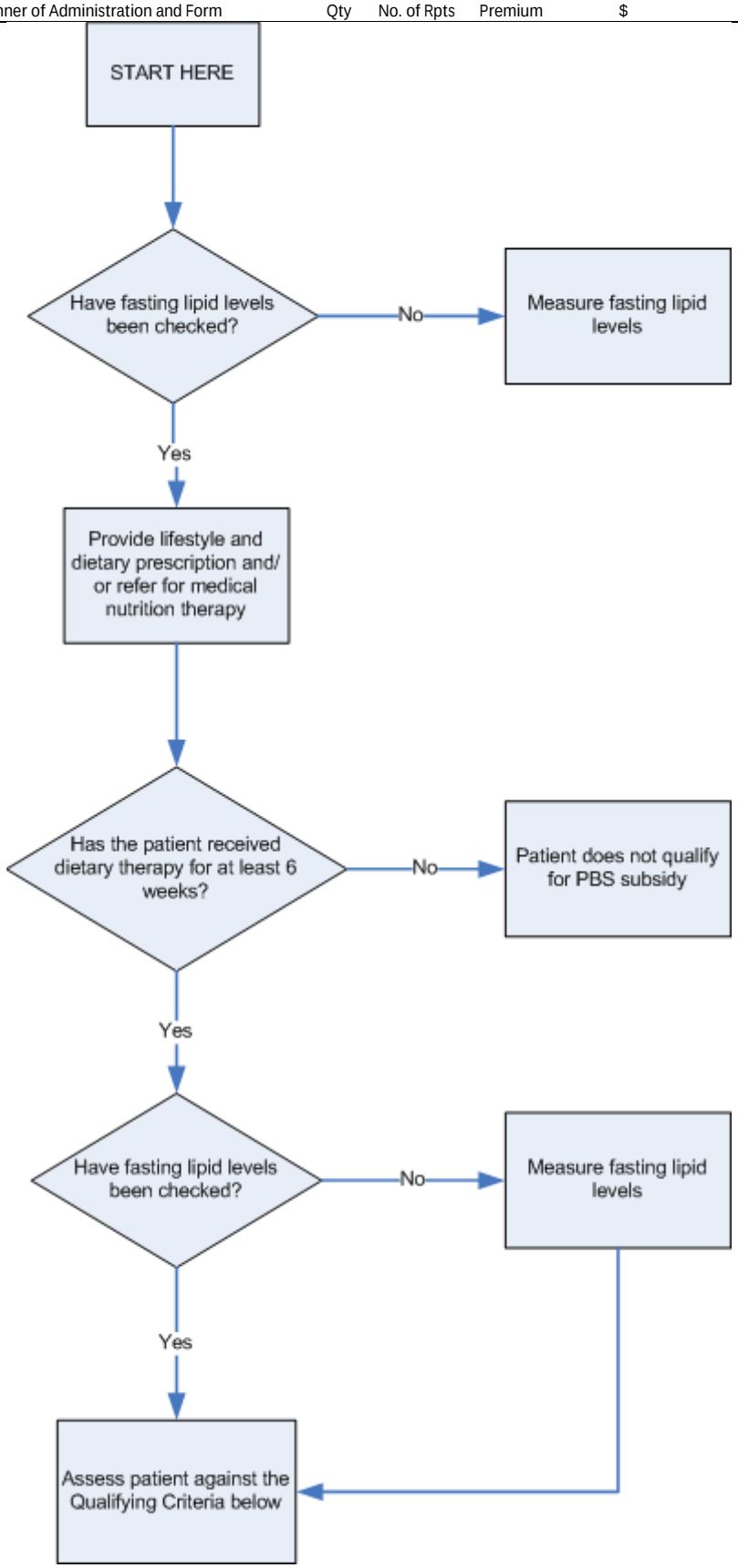
Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio of > 2.5 for males, > 3.5 for females)
- diabetes mellitus in Aboriginal or Torres Strait Islander patients
- diabetes mellitus in patients aged 60 years or more
- family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives
- family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives

If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer



Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

POST-DIETARY QUALIFYING CRITERIA

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

PATIENT CATEGORY	LIPID LEVELS FOR PBS SUBSIDY
Patients with diabetes mellitus not otherwise included	total cholesterol > 5.5 mmol/L
Aboriginal or Torres Strait Islander patients Patients with hypertension	total cholesterol > 6.5 mmol/L or total cholesterol > 5.5 mmol/L and HDL cholesterol < 1 mmol/L
Patients with HDL cholesterol < 1 mmol/L	total cholesterol > 6.5 mmol/L
Patients with familial hypercholesterolaemia identified by: • DNA mutation; or • tendon xanthomas in the patient or their first or second degree relative Patients with: • family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or • family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives	If aged 18 years or less at treatment initiation: LDL cholesterol > 4 mmol/L If aged more than 18 years at treatment initiation: LDL cholesterol > 5 mmol/L or total cholesterol > 6.5 mmol/L or total cholesterol > 5.5 mmol/L and HDL cholesterol < 1 mmol/L
Patients not eligible under the above: • men aged 35 to 75 years • post-menopausal women aged up to 75 years	total cholesterol > 7.5 mmol/L or triglyceride > 4 mmol/L
Patients not otherwise included	total cholesterol > 9 mmol/L or triglyceride > 8 mmol/L

Lipid modifying agents

Lipid modifying agents, plain

HMG CoA reductase inhibitors

ATORVASTATIN

Restricted benefit

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8213G *NP*	Tablet 10 mg (as calcium)	30	5	..	37.13	35.40	a	APO-Atorvastatin	TX
							a	Atorvachol	GM
							a	Atorvastatin GH	GQ
							a	Atorvastatin Pfizer	FZ
							a	Atorvastatin Sandoz	SZ
							a	Chem mart Atorvastatin	CH
							a	Lipitor	PF
							a	Lorstat 10	AF
							a	Terry White Chemists Atorvastatin	TW
							a	Torvastat 10	QA

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Trovas	RA
8214H *NP*	Tablet 20 mg (as calcium)	30	5	..	50.31	35.40	[a]	APO-Atorvastatin	TX
							[a]	Atorvachol	GM
							[a]	Atorvastatin GH	GQ
							[a]	Atorvastatin Pfizer	FZ
							[a]	Atorvastatin Sandoz	SZ
							[a]	Chem mart Atorvastatin	CH
							[a]	Lipitor	PF
							[a]	Lorstat 20	AF
							[a]	Terry White Chemists Atorvastatin	TW
							[a]	Torvastat 20	QA
							[a]	Trovas	RA
8215J *NP*	Tablet 40 mg (as calcium)	30	5	..	67.44	35.40	[a]	APO-Atorvastatin	TX
							[a]	Atorvachol	GM
							[a]	Atorvastatin GH	GQ
							[a]	Atorvastatin Pfizer	FZ
							[a]	Atorvastatin Sandoz	SZ
							[a]	Chem mart Atorvastatin	CH
							[a]	Lipitor	PF
							[a]	Lorstat 40	AF
							[a]	Terry White Chemists Atorvastatin	TW
							[a]	Torvastat 40	QA
							[a]	Trovas	RA
8521L *NP*	Tablet 80 mg (as calcium)	30	5	..	93.64	35.40	[a]	APO-Atorvastatin	TX
							[a]	Atorvachol	GM
							[a]	Atorvastatin GH	GQ
							[a]	Atorvastatin Pfizer	FZ
							[a]	Atorvastatin Sandoz	SZ
							[a]	Chem mart Atorvastatin	CH
							[a]	Lipitor	PF
							[a]	Lorstat 80	AF
							[a]	Terry White Chemists Atorvastatin	TW
							[a]	Torvastat 80	QA
							[a]	Trovas	RA

ATORVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
9230T	Tablet 10 mg (as calcium)	30	11	..	37.13	35.40	a	APO-Atorvastatin	TX
							a	Atorvachol	GM
							a	Atorvastatin GH	GQ
							a	Atorvastatin Pfizer	FZ
							a	Atorvastatin Sandoz	SZ
							a	Chem mart Atorvastatin	CH
							a	Lipitor	PF
							a	Lorstat 10	AF
							a	Terry White Chemists Atorvastatin	TW
							a	Torvastat 10	QA
							a	Trovas	RA
9231W	Tablet 20 mg (as calcium)	30	11	..	50.31	35.40	a	APO-Atorvastatin	TX
							a	Atorvachol	GM
							a	Atorvastatin GH	GQ
							a	Atorvastatin Pfizer	FZ
							a	Atorvastatin Sandoz	SZ
							a	Chem mart Atorvastatin	CH
							a	Lipitor	PF
							a	Lorstat 20	AF
							a	Terry White Chemists Atorvastatin	TW
							a	Torvastat 20	QA
							a	Trovas	RA
9232X	Tablet 40 mg (as calcium)	30	11	..	67.44	35.40	a	APO-Atorvastatin	TX
							a	Atorvachol	GM
							a	Atorvastatin GH	GQ
							a	Atorvastatin Pfizer	FZ
							a	Atorvastatin Sandoz	SZ
							a	Chem mart Atorvastatin	CH
							a	Lipitor	PF
							a	Lorstat 40	AF
							a	Terry White Chemists Atorvastatin	TW
							a	Torvastat 40	QA
							a	Trovas	RA
9233Y	Tablet 80 mg (as calcium)	30	11	..	93.64	35.40	a	APO-Atorvastatin	TX
							a	Atorvachol	GM
							a	Atorvastatin GH	GQ
							a	Atorvastatin Pfizer	FZ
							a	Atorvastatin Sandoz	SZ
							a	Chem mart Atorvastatin	CH
							a	Lipitor	PF
							a	Lorstat 80	AF
							a	Terry White Chemists Atorvastatin	TW

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Torvastat 80	QA
							[a]	Trovas	RA
	FLUVASTATIN **Restricted benefit** For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.								
2863Q *NP*	Tablet (prolonged release) 80 mg (as sodium)	28	5	..	45.42	35.40		Lescol XL	NV
8023G *NP*	Capsule 20 mg (as sodium)	28	5	..	25.46	26.55	[a]	Lescol	NV
				[B]3.09	28.55	26.55	[a]	Vastin	NM
8024H *NP*	Capsule 40 mg (as sodium)	28	5	..	29.77	30.86	[a]	Lescol	NV
				[B]3.36	33.13	30.86	[a]	Vastin	NM
	FLUVASTATIN **Restricted benefit** For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. **Note** No applications for increased maximum quantities and/or repeats will be authorised.								
9234B	Capsule 20 mg (as sodium)	28	11	..	25.46	26.55	[a]	Lescol	NV
				[B]3.09	28.55	26.55	[a]	Vastin	NM
9235C	Capsule 40 mg (as sodium)	28	11	..	29.77	30.86	[a]	Lescol	NV
				[B]3.36	33.13	30.86	[a]	Vastin	NM
9236D	Tablet (prolonged release) 80 mg (as sodium)	28	11	..	45.42	35.40		Lescol XL	NV
	PRAVASTATIN **Restricted benefit** For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.								
2833D *NP*	Tablet containing pravastatin sodium 10 mg	30	5	..	13.62	14.71	[a]	APO-Pravastatin	TX
							[a]	Chem mart Pravastatin	CH
							[a]	Cholstat 10	AF
							[a]	GenRx Pravastatin	GX
							[a]	Lipostat 10	QA
							[a]	Pharmacor Pravastat 10	CR
							[a]	Pravastatin Actavis 10	TA
							[a]	Pravastatin-GA 10	GM
							[a]	Pravastatin generichealth	GQ
							[a]	Pravastatin Sandoz	SZ
							[a]	Pravastatin Winthrop	WA
							[a]	Terry White Chemists Pravastatin	TW
				[B]1.97	15.59	14.71	[a]	Pravachol	FM
2834E *NP*	Tablet containing pravastatin sodium 20 mg	30	5	..	17.87	18.96	[a]	APO-Pravastatin	TX
							[a]	Chem mart Pravastatin	CH
							[a]	Cholstat 20	AF

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Cholvastin	RA
							[a]	GenRx Pravastatin	GX
							[a]	Lipostat 20	QA
							[a]	Pharmacor Pravastat 20	CR
							[a]	Pravastatin Actavis 20	TA
							[a]	Pravastatin-GA 20	GM
							[a]	Pravastatin generichealth	GQ
							[a]	Pravastatin Sandoz	SZ
							[a]	Pravastatin Winthrop	WA
							[a]	Terry White Chemists Pravastatin	TW
				[B]2.01	19.88	18.96	[a]	Pravachol	FM
8197K *NP*	Tablet containing pravastatin sodium 40 mg	30	5	..	24.23	25.32	[a]	APO-Pravastatin	TX
							[a]	Chem mart Pravastatin	CH
							[a]	Cholstat 40	AF
							[a]	Cholvastin	RA
							[a]	GenRx Pravastatin	GX
							[a]	Lipostat 40	QA
							[a]	Pharmacor Pravastat 40	CR
							[a]	Pravastatin Actavis 40	TA
							[a]	Pravastatin-GA 40	GM
							[a]	Pravastatin generichealth	GQ
							[a]	Pravastatin Sandoz	SZ
							[a]	Pravastatin Winthrop	WA
							[a]	Terry White Chemists Pravastatin	TW
				[B]2.42	26.65	25.32	[a]	Pravachol	FM
8829Q *NP*	Tablet containing pravastatin sodium 80 mg	30	5	..	33.81	34.90	[a]	APO-Pravastatin	TX
							[a]	Chem mart Pravastatin	CH
							[a]	Lipostat 80	QA
							[a]	Pravastatin-GA 80	GM
							[a]	Pravastatin generichealth	GQ
							[a]	Pravastatin Sandoz	SZ
							[a]	Terry White Chemists Pravastatin	TW
				[B]2.17	35.98	34.90	[a]	Pravachol	FM

PRAVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
9237E	Tablet containing pravastatin sodium 10 mg	30	11	..	13.62	14.71	a	APO-Pravastatin	TX
							a	Chem mart Pravastatin	CH
							a	Cholstat 10	AF
							a	GenRx Pravastatin	GX
							a	Lipostat 10	QA
							a	Pharmacor Pravastat 10	CR
							a	Pravastatin Actavis 10	TA
							a	Pravastatin-GA 10	GM
							a	Pravastatin generichealth	GQ
							a	Pravastatin Sandoz	SZ
							a	Pravastatin Winthrop	WA
							a	Terry White Chemists Pravastatin	TW
				B1.97	15.59	14.71	a	Pravachol	FM
9238F	Tablet containing pravastatin sodium 20 mg	30	11	..	17.87	18.96	a	APO-Pravastatin	TX
							a	Chem mart Pravastatin	CH
							a	Cholstat 20	AF
							a	Cholvastin	RA
							a	GenRx Pravastatin	GX
							a	Lipostat 20	QA
							a	Pharmacor Pravastat 20	CR
							a	Pravastatin Actavis 20	TA
							a	Pravastatin-GA 20	GM
							a	Pravastatin generichealth	GQ
							a	Pravastatin Sandoz	SZ
							a	Pravastatin Winthrop	WA
							a	Terry White Chemists Pravastatin	TW
				B2.01	19.88	18.96	a	Pravachol	FM
9239G	Tablet containing pravastatin sodium 40 mg	30	11	..	24.23	25.32	a	APO-Pravastatin	TX
							a	Chem mart Pravastatin	CH
							a	Cholstat 40	AF
							a	Cholvastin	RA
							a	GenRx Pravastatin	GX
							a	Lipostat 40	QA
							a	Pharmacor Pravastat 40	CR
							a	Pravastatin Actavis 40	TA
							a	Pravastatin-GA 40	GM
							a	Pravastatin generichealth	GQ
							a	Pravastatin Sandoz	SZ
							a	Pravastatin Winthrop	WA
							a	Terry White Chemists Pravastatin	TW

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
				[B]2.42	26.65	25.32	[a]	Pravachol	FM
9240H	Tablet containing pravastatin sodium 80 mg	30	11	..	33.81	34.90	[a]	APO-Pravastatin	TX
							[a]	Chem mart Pravastatin	CH
							[a]	Lipostat 80	QA
							[a]	Pravastatin-GA 80	GM
							[a]	Pravastatin generichealth	GQ
							[a]	Pravastatin Sandoz	SZ
							[a]	Terry White Chemists Pravastatin	TW
				[B]2.17	35.98	34.90	[a]	Pravachol	FM

ROSUVASTATIN
Restricted benefit
For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

9042X *NP*	Tablet 5 mg (as calcium)	30	5	..	39.45	35.40		Crestor	AP
9043Y *NP*	Tablet 10 mg (as calcium)	30	5	..	53.06	35.40		Crestor	AP
9044B *NP*	Tablet 20 mg (as calcium)	30	5	..	72.42	35.40		Crestor	AP
9045C *NP*	Tablet 40 mg (as calcium)	30	5	..	100.56	35.40		Crestor	AP

ROSUVASTATIN
Restricted benefit
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

3402C	Tablet 5 mg (as calcium)	30	11	..	39.45	35.40		Crestor	AP
3403D	Tablet 10 mg (as calcium)	30	11	..	53.06	35.40		Crestor	AP
3404E	Tablet 20 mg (as calcium)	30	11	..	72.42	35.40		Crestor	AP
3405F	Tablet 40 mg (as calcium)	30	11	..	100.56	35.40		Crestor	AP

SIMVASTATIN
Restricted benefit
For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

2011W *NP*	Tablet 10 mg	30	5	..	14.27	15.36	[a]	APO-Simvastatin	TX
							[a]	Auro-Simvastatin 10	DO
							[a]	Chem mart Simvastatin	CH
							[a]	GenRx Simvastatin	GX
							[a]	Pharmacor Simvastatin 10	MI
							[a]	Ransim	RA
							[a]	Simvacor 10	CR
							[a]	Simvahexal	HX
							[a]	Simvar 10	QA
							[a]	Simvastatin-DP	GM
							[a]	Simvastatin-GA 10	GN

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Simvastatin genericheath	GQ
							[a]	Simvastatin Pfizer	FZ
							[a]	Simvastatin Sandoz	SZ
							[a]	Simvastatin-Spirit 10	ZP
							[a]	Simvastatin Winthrop	WA
							[a]	Synthon Simvastatin	ZT
							[a]	Terry White Chemists Simvastatin	TW
							[a]	Zimstat	AF
				[B]1.76	16.03	15.36	[a]	Lipex 10	FR
							[a]	Zocor	MK
2012X *NP*	Tablet 20 mg	30	5	..	17.72	18.81	[a]	APO-Simvastatin	TX
							[a]	Auro-Simvastatin 20	DO
							[a]	Chem mart Simvastatin	CH
							[a]	GenRx Simvastatin	GX
							[a]	Pharmacor Simvastatin 20	MI
							[a]	Ransim	RA
							[a]	Simvacor 20	CR
							[a]	Simvahexal	HX
							[a]	Simvar 20	QA
							[a]	Simvastatin-DP	GM
							[a]	Simvastatin-GA 20	GN
							[a]	Simvastatin genericheath	GQ
							[a]	Simvastatin Pfizer	FZ
							[a]	Simvastatin Sandoz	SZ
							[a]	Simvastatin-Spirit 20	ZP
							[a]	Simvastatin Winthrop	WA
							[a]	Synthon Simvastatin	ZT
							[a]	Terry White Chemists Simvastatin	TW
							[a]	Zimstat	AF
				[B]1.76	19.48	18.81	[a]	Lipex 20	FR
							[a]	Zocor	MK
2013Y *NP*	Tablet 5 mg	30	5	..	12.10	13.19	[a]	Simvahexal	HX
							[a]	Simvastatin Sandoz	SZ
							[a]	Zimstat	AF
				[B]1.76	13.86	13.19	[a]	Zocor	MK
8173E *NP*	Tablet 40 mg	30	5	..	22.68	23.77	[a]	APO-Simvastatin	TX
							[a]	Auro-Simvastatin 40	DO
							[a]	Chem mart Simvastatin	CH
							[a]	GenRx Simvastatin	GX
							[a]	Pharmacor Simvastatin 40	MI

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Ransim	RA
							[a]	Simvacor 40	CR
							[a]	Simvahexal	HX
							[a]	Simvar 40	QA
							[a]	Simvastatin-DP	GM
							[a]	Simvastatin-GA 40	GN
							[a]	Simvastatin generichealth	GQ
							[a]	Simvastatin Pfizer	FZ
							[a]	Simvastatin Sandoz	SZ
							[a]	Simvastatin-Spirit 40	ZP
							[a]	Simvastatin Winthrop	WA
							[a]	Synthon Simvastatin	ZT
							[a]	Terry White Chemists Simvastatin	TW
							[a]	Zimstat	AF
				[B]2.03	24.71	23.77	[a]	Lipex 40	FR
							[a]	Zocor	MK
8313M *NP*	Tablet 80 mg	30	5	..	29.79	30.88	[a]	APO-Simvastatin	TX
							[a]	Auro-Simvastatin 80	DO
							[a]	Chem mart Simvastatin	CH
							[a]	GenRx Simvastatin	GX
							[a]	Pharmacor Simvastatin 80	MI
							[a]	Ransim	RA
							[a]	Simvacor 80	CR
							[a]	Simvar 80	QA
							[a]	Simvastatin-DP	GM
							[a]	Simvastatin-GA 80	GN
							[a]	Simvastatin generichealth	GQ
							[a]	Simvastatin Pfizer	FZ
							[a]	Simvastatin Sandoz	SZ
							[a]	Simvastatin-Spirit 80	ZP
							[a]	Simvastatin Winthrop	WA
							[a]	Synthon Simvastatin	ZT
							[a]	Terry White Chemists Simvastatin	TW
							[a]	Zimstat	AF
				[B]1.84	31.63	30.88	[a]	Lipex 80	FR
							[a]	Zocor	MK

SIMVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9241J	Tablet 5 mg	30	11	..	12.10	13.19	a	Simvahexal	HX
							a	Simvastatin Sandoz	SZ
							a	Zimstat	AF
				B1.76	13.86	13.19	a	Zocor	MK
9242K	Tablet 10 mg	30	11	..	14.27	15.36	a	APO-Simvastatin	TX
							a	Auro-Simvastatin 10	DO
							a	Chem mart Simvastatin	CH
							a	GenRx Simvastatin	GX
							a	Pharmacor Simvastatin 10	MI
							a	Ransim	RA
							a	Simvacor 10	CR
							a	Simvahexal	HX
							a	Simvar 10	QA
							a	Simvastatin-DP	GM
							a	Simvastatin-GA 10	GN
							a	Simvastatin generichealth	GQ
							a	Simvastatin Pfizer	FZ
							a	Simvastatin Sandoz	SZ
							a	Simvastatin-Spirit 10	ZP
							a	Simvastatin Winthrop	WA
							a	Synthon Simvastatin	ZT
							a	Terry White Chemists Simvastatin	TW
							a	Zimstat	AF
				B1.76	16.03	15.36	a	Lipex 10	FR
							a	Zocor	MK
9243L	Tablet 20 mg	30	11	..	17.72	18.81	a	APO-Simvastatin	TX
							a	Auro-Simvastatin 20	DO
							a	Chem mart Simvastatin	CH
							a	GenRx Simvastatin	GX
							a	Pharmacor Simvastatin 20	MI
							a	Ransim	RA
							a	Simvacor 20	CR
							a	Simvahexal	HX
							a	Simvar 20	QA
							a	Simvastatin-DP	GM
							a	Simvastatin-GA 20	GN
							a	Simvastatin generichealth	GQ
							a	Simvastatin Pfizer	FZ
							a	Simvastatin Sandoz	SZ
							a	Simvastatin-Spirit 20	ZP
							a	Simvastatin Winthrop	WA
							a	Synthon	ZT

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Simvastatin	
							a	Terry White Chemists Simvastatin	TW
							a	Zimstat	AF
				[B]1.76	19.48	18.81	a	Lipex 20	FR
							a	Zocor	MK
9244M	Tablet 40 mg	30	11	..	22.68	23.77	a	APO-Simvastatin	TX
							a	Auro-Simvastatin 40	DO
							a	Chem mart Simvastatin	CH
							a	GenRx Simvastatin	GX
							a	Pharmacor Simvastatin 40	MI
							a	Ransim	RA
							a	Simvacor 40	CR
							a	Simvahexal	HX
							a	Simvar 40	QA
							a	Simvastatin-DP	GM
							a	Simvastatin-GA 40	GN
							a	Simvastatin generichealth	GQ
							a	Simvastatin Pfizer	FZ
							a	Simvastatin Sandoz	SZ
							a	Simvastatin-Spirit 40	ZP
							a	Simvastatin Winthrop	WA
							a	Synthon Simvastatin	ZT
							a	Terry White Chemists Simvastatin	TW
							a	Zimstat	AF
				[B]2.03	24.71	23.77	a	Lipex 40	FR
							a	Zocor	MK
9245N	Tablet 80 mg	30	11	..	29.79	30.88	a	APO-Simvastatin	TX
							a	Auro-Simvastatin 80	DO
							a	Chem mart Simvastatin	CH
							a	GenRx Simvastatin	GX
							a	Pharmacor Simvastatin 80	MI
							a	Ransim	RA
							a	Simvacor 80	CR
							a	Simvar 80	QA
							a	Simvastatin-DP	GM
							a	Simvastatin-GA 80	GN
							a	Simvastatin generichealth	GQ
							a	Simvastatin Pfizer	FZ
							a	Simvastatin Sandoz	SZ
							a	Simvastatin-Spirit 80	ZP
							a	Simvastatin Winthrop	WA
							a	Synthon Simvastatin	ZT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Terry White Chemists Simvastatin	TW
							[a]	Zimstat	AF
				[B]1.84	31.63	30.88	[a]	Lipex 80	FR
							[a]	Zocor	MK

Fibrates

FENOFIBRATE

Note

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

9022W *NP*	Tablet 48 mg	60	5	..	30.05	31.14		Lipidil	AB
9023X *NP*	Tablet 145 mg	30	5	..	41.75	35.40		Lipidil	AB

FENOFIBRATE

Note

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9246P	Tablet 48 mg	60	11	..	30.05	31.14		Lipidil	AB
9247Q	Tablet 145 mg	30	11	..	41.75	35.40		Lipidil	AB

GEMFIBROZIL

Note

The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

1453L *NP*	Tablet 600 mg	60	5	..	22.04	23.13	[a]	Ausgem	QA
							[a]	Chem mart Gemfibrozil	CH
							[a]	Gemhexal	SZ
							[a]	GenRx Gemfibrozil	GX
							[a]	Jezil	GN
							[a]	Lipazil 600 mg	GM
							[a]	Lipigem	AF
							[a]	Pharmacor Gemfibrozil 600	CR
							[a]	Terry White Chemists Gemfibrozil	TW
				[B]1.98	24.02	23.13	[a]	Lopid	PF

Cardiovascular system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	GEMFIBROZIL								
	Note								
	The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.								
	Restricted benefit								
	For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9248R	Tablet 600 mg	60	11	..	22.04	23.13	[a]	Ausgem	QA
							[a]	Chem mart Gemfibrozil	CH
							[a]	Gemhexal	SZ
							[a]	GenRx Gemfibrozil	GX
							[a]	Jezil	GN
							[a]	Lipazil 600 mg	GM
							[a]	Lipigem	AF
							[a]	Pharmacor Gemfibrozil 600	CR
							[a]	Terry White Chemists Gemfibrozil	TW
				[B]1.98	24.02	23.13	[a]	Lopid	PF

Bile acid sequestrants

	CHOLESTYRAMINE								
2967E *NP*	Sachets 4.7 g (equivalent to 4 g cholestyramine), 50	2	5	..	*71.94	35.40		Questran Lite	QA
	CHOLESTYRAMINE								
	Restricted benefit								
	For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9249T	Sachets 4.7 g (equivalent to 4 g cholestyramine), 50	2	11	..	*71.94	35.40		Questran Lite	QA
	COLESTIPOL HYDROCHLORIDE								
1224K *NP*	Sachets 5 g, 120	‡1	5	..	85.04	35.40		Colestid	PF
	COLESTIPOL HYDROCHLORIDE								
	Restricted benefit								
	For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9250W	Sachets 5 g, 120	‡1	11	..	85.04	35.40		Colestid	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Other lipid modifying agents

EZETIMIBE

Authority required (STREAMLINED)

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have:

3724

(a) coronary heart disease; or

3725

(b) diabetes mellitus; or

3726

(c) peripheral vascular disease; or

3727

(d) heterozygous familial hypercholesterolaemia; or

3728

(e) symptomatic cerebrovascular disease; or

3729

(f) family history of coronary heart disease; or

3730

(g) hypertension.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

1989

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated;

3731

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced because the patient developed a clinically important product-related adverse event during treatment with a statin.
A clinically important product-related adverse event is defined as follows:
(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Authority required (STREAMLINED)

1991

Homozygous sitosterolaemia;

2438

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin).

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8757X *NP*	Tablet 10 mg	30	5	..	70.97	35.40	Ezetrol	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Lipid modifying agents, combinations

HMG CoA reductase inhibitors in combination with other lipid modifying agents

EZETIMIBE with SIMVASTATIN

Authority required (STREAMLINED)

2431

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs);

3739

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be reduced because the patient developed a clinically important product-related adverse event during treatment with a statin.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9483D *NP*	Tablet 10 mg-10 mg	30	5	..	88.79	35.40	Vytorin	MK
9484E *NP*	Tablet 10 mg-20 mg	30	5	..	96.59	35.40	Vytorin	MK

EZETIMIBE with SIMVASTATIN

Authority required (STREAMLINED)

Treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who have:

3732

(a) coronary heart disease; or

3733

(b) diabetes mellitus; or

3734

(c) peripheral vascular disease; or

3735

(d) heterozygous familial hypercholesterolaemia; or

3736

(e) cerebrovascular disease which has become symptomatic; or

3737

(f) family history of coronary heart disease; or

3738

(g) hypertension;

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated.

2431

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note								
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8881K *NP*	Tablet 10 mg-40 mg	30	5	..	107.85	35.40		Vytorin	MK
8882L *NP*	Tablet 10 mg-80 mg	30	5	..	123.97	35.40		Vytorin	MK

HMG CoA reductase inhibitors, other combinations

AMLODIPINE BESYLATE with ATORVASTATIN CALCIUM

Restricted benefit

For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and:
(a) who are currently receiving treatment with a dihydropyridine calcium channel blocker; OR

(b) whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate; OR

(c) who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

9049G *NP*	Tablet 5 mg (base)-10 mg (base)	30	5	..	42.00	35.40	[a]	Cadatin 5/10	FZ
							[a]	Caduet 5/10	PF
9050H *NP*	Tablet 5 mg (base)-20 mg (base)	30	5	..	54.69	35.40	[a]	Cadatin 5/20	FZ
							[a]	Caduet 5/20	PF
9051J *NP*	Tablet 5 mg (base)-40 mg (base)	30	5	..	72.26	35.40	[a]	Cadatin 5/40	FZ
							[a]	Caduet 5/40	PF
9052K *NP*	Tablet 5 mg (base)-80 mg (base)	30	5	..	98.46	35.40	[a]	Cadatin 5/80	FZ
							[a]	Caduet 5/80	PF
9053L *NP*	Tablet 10 mg (base)-10 mg (base)	30	5	..	45.30	35.40	[a]	Cadatin 10/10	FZ
							[a]	Caduet 10/10	PF
9054M *NP*	Tablet 10 mg (base)-20 mg (base)	30	5	..	58.20	35.40	[a]	Cadatin 10/20	FZ
							[a]	Caduet 10/20	PF
9055N *NP*	Tablet 10 mg (base)-40 mg (base)	30	5	..	75.89	35.40	[a]	Cadatin 10/40	FZ
							[a]	Caduet 10/40	PF
9056P *NP*	Tablet 10 mg (base)-80 mg (base)	30	5	..	102.09	35.40	[a]	Cadatin 10/80	FZ
							[a]	Caduet 10/80	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Dermatologicals

Antifungals for dermatological use

Antifungals for topical use

Antibiotics

NYSTATIN
Authority required (STREAMLINED)
2354
Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.

1698J *NP*	Cream 100,000 units per g, 15 g	2	3	..	*18.56	19.65	Mycostatin	FM

Imidazole and triazole derivatives

KETOCONAZOLE
Authority required (STREAMLINED)
2354
Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.

1574W *NP*	Shampoo 20 mg per g (2%), 60 mL	‡1	1	..	18.31	19.40	Nizoral 2%	JT
9024Y *NP*	Cream 20 mg per g (2%), 30 g	‡1	2	..	23.12	24.21	Nizoral 2% Cream	JT
9025B *NP*	Shampoo 10 mg per g (1%), 100 mL	‡1	1	..	17.60	18.69	Nizoral 1%	JT

MICONAZOLE
Authority required (STREAMLINED)
2354
Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.

9031H *NP*	Tincture 20 mg per mL (2%), 30 mL	‡1	2	..	19.47	20.56	Daktarin	JT

MICONAZOLE NITRATE
Authority required (STREAMLINED)
2354
Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.

9026C *NP*	Cream 20 mg per g (2%), 15 g	2	3	..	*15.90	16.99	Daktarin	JT
9027D *NP*	Cream 20 mg per g (2%), 30 g	‡1	2	..	14.79	15.88	Daktarin	JT
9028E *NP*	Cream 20 mg per g (2%), 70 g	‡1	1	..	16.79	17.88	Daktarin	JT
9029F *NP*	Powder 20 mg per g (2%), 30 g	‡1	2	..	15.56	16.65	Daktarin	JT
9030G *NP*	Lotion 20 mg per mL (2%), 30 g	‡1	2	..	16.72	17.81	Daktarin	JT

Other antifungals for topical use

TERBINAFINE
Authority required (STREAMLINED)
2354
Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person;

3243
Treatment of a fungal or a yeast infection in a patient aged up to 18 years inclusive.

9160D *NP*	Cream containing terbinafine hydrochloride 10 mg per g (1%), 15 g	2	3	..	*37.36	35.40	Lamisil	NC

Dermatologicals

Antifungals for systemic use
Antifungals for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	GRISEOFULVIN								
1460W *NP*	Tablet 125 mg	100	2	..	25.87	26.96		Grisovin	QA
2982Y *NP*	Tablet 500 mg	28	2	..	26.99	28.08		Grisovin 500	QA
	TERBINAFINE **Authority required** Treatment of a dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed; Treatment of a dermatophyte infection in a patient aged up to 18 years inclusive where topical treatment and griseofulvin have failed.								
2285G *NP*	Tablet 250 mg (as hydrochloride)	42	..	..	69.20	35.40	[a]	GenRx Terbinafine	GX
							[a]	Lamisil (Novartis Pharmaceuticals Australia Pty Limited)	NV
							[a]	Sebifin 250	RA
							[a]	Tamsil	QA
							[a]	Terbihexal	SZ
							[a]	Terbinafine 250	CR
							[a]	Terbinafine-DRLA	RZ
							[a]	Terbinafine-GA	GM
							[a]	Terbix 250	MI
							[a]	Tinasil	AF
	TERBINAFINE **Authority required** Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed. This infection must be proven by microscopy or culture and confirmed by an Approved Pathology Authority. The date of the pathology report must be provided at the time of application and must not be more than 12 months old. **Note** No applications for increased maximum quantities and/or repeats will be authorised.									
2804N *NP*	Tablet 250 mg (as hydrochloride)	42	1	..	69.20	35.40	[a]	GenRx Terbinafine	GX
							[a]	Lamisil (Novartis Pharmaceuticals Australia Pty Limited)	NV
							[a]	Sebifin 250	RA
							[a]	Tamsil	QA
							[a]	Terbihexal	SZ
							[a]	Terbinafine 250	CR
							[a]	Terbinafine-DRLA	RZ
							[a]	Terbinafine-GA	GM
							[a]	Terbix 250	MI
							[a]	Tinasil	AF

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
Antipsoriatics								
Antipsoriatics for topical use								
Tars								
	COAL TAR - PREPARED							
8864M *NP*	Gel 10 mg per g (1%), 100 mL	‡1	2	..	33.08	34.17	Exorex	GM
Other antipsoriatics for topical use								
	CALCIPOTRIOL **Restricted benefit** Chronic stable plaque type psoriasis vulgaris. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2080L *NP*	Cream 50 micrograms per g (0.005%), 30 g	‡1	1	..	28.06	29.15	Daivonex	LO
	CALCIPOTRIOL **Restricted benefit** Chronic stable plaque type psoriasis vulgaris of the scalp. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9163G *NP*	Scalp solution 50 micrograms per mL (0.005%), 30 mL	‡1	1	..	28.06	29.15	Daivonex	LO
	CALCIPOTRIOL with BETAMETHASONE DIPROPIONATE **Restricted benefit** Chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9494Q *NP*	Ointment 50 micrograms-500 micrograms (base) per g (0.005%-0.05%), 30 g	‡1	1	..	41.89	35.40	Daivobet	LO
	CALCIPOTRIOL with BETAMETHASONE DIPROPIONATE **Restricted benefit** Chronic stable plaque type psoriasis vulgaris of the scalp in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5276Q *NP*	Gel 50 micrograms-500 micrograms (base) per g (0.005%-0.05%), 30 g	‡1	1	..	41.89	35.40	Daivobet 50/500 gel	LO

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Antipsoriatics for systemic use								
	Retinoids for treatment of psoriasis								
	ACITRETIN								
	Caution								
	This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.								
	Note								
	Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.								
	Authority required (STREAMLINED)								
	1366								
	Severe intractable psoriasis;								
	1363								
	Severe forms of disorders of keratinisation.								
2019G	Capsule 10 mg	100	2	..	205.77	35.40		Neotigason	TA
2020H	Capsule 25 mg	100	2	..	393.21	35.40		Neotigason	TA
	Antibiotics and chemotherapeutics for dermatological use								
	Chemotherapeutics for topical use								
	Sulfonamides								
	SILVER SULFADIAZINE								
	Restricted benefit								
	Prevention and treatment of infection in partial or full skin thickness loss due to burns;								
	Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa;								
	Stasis ulcers.								
9479X *NP*	Cream 10 mg per g (1%), 50 g	‡1	..	..	19.15	20.24		Flamazine	SN
	Corticosteroids, dermatological preparations								
	Corticosteroids, plain								
	Corticosteroids, weak (group I)								
	HYDROCORTISONE ACETATE								
	Restricted benefit								
	Treatment of corticosteroid-responsive dermatoses.								
2881P *NP*	Cream 10 mg per g (1%), 50 g	‡1	1	..	8.56	9.65	a	Cortic-DS 1%	FM
				B2.70	11.26	9.65	a	Sigmacort	QA
2882Q *NP*	Topical ointment 10 mg per g (1%), 50 g	‡1	1	..	8.56	9.65	a	Cortic-DS 1%	FM
				B2.70	11.26	9.65	a	Sigmacort	QA
2887Y *NP*	Cream 10 mg per g (1%), 30 g	‡1	1	..	8.89	9.98	a	Cortic-DS 1%	FM
				B2.69	11.58	9.98	a	Sigmacort	QA
2888B *NP*	Topical ointment 10 mg per g (1%), 30 g	‡1	1	..	8.89	9.98	a	Cortic-DS 1%	FM
				B2.69	11.58	9.98	a	Sigmacort	QA
	Corticosteroids, moderately potent (group II)								
	TRIAMCINOLONE ACETONIDE								
	Restricted benefit								
	Treatment of corticosteroid-responsive dermatoses.								
2117K *NP*	Cream 200 micrograms per g (0.02%), 100 g	2	..	..	*14.40	15.49	a	Tricortone	FM
				B3.78	*18.18	15.49	a	Aristocort 0.02%	QA
2118L	Ointment 200 micrograms per g (0.02%), 100 g	2	..	..	*14.40	15.49	a	Tricortone	FM

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP				[B]3.78	*18.18	15.49	[a]	Aristocort 0.02%	QA

Corticosteroids, potent (group III)

BETAMETHASONE DIPROPIONATE
Restricted benefit
Treatment of corticosteroid-responsive dermatoses.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1115Q *NP*	Cream 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	13.14	14.23	[a]	Eleuphrat	FR
				[B]2.45	15.59	14.23	[a]	Diprosone	MK
1119X *NP*	Ointment 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	13.14	14.23	[a]	Eleuphrat	FR
				[B]2.45	15.59	14.23	[a]	Diprosone	MK

BETAMETHASONE VALERATE
Restricted benefit
Treatment of corticosteroid-responsive dermatoses.

2812B *NP*	Cream 200 micrograms (base) per g (0.02%), 100 g	2	..	..	*24.22	25.31	[a]	Antroquoril	FR
							[b]	Cortival 1/5	FM
				[B]2.46	*26.68	25.31	[a]	Celestone-M	MK
				[B]6.88	*31.10	25.31	[b]	Betnovate 1/5	QA
2820K *NP*	Ointment 200 micrograms (base) per g (0.02%), 100 g	2	..	..	*24.22	25.31	[a]	Antroquoril	FR
				[B]2.46	*26.68	25.31	[a]	Celestone-M	MK

BETAMETHASONE VALERATE
Restricted benefit
Treatment of corticosteroid-responsive dermatoses.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2813C *NP*	Cream 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	8.41	9.50	[b]	Cortival 1/2	FM
				[B]2.94	11.35	9.50	[b]	Betnovate 1/2	QA
2815E *NP*	Ointment 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	8.41	9.50	[b]	Cortival 1/2	FM
				[B]2.94	11.35	9.50	[b]	Betnovate 1/2	QA

METHYLPREDNISOLONE ACEPONATE
Restricted benefit
Treatment of corticosteroid-responsive dermatoses.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8054X *NP*	Cream 1 mg per g (0.1%), 15 g	‡1	..	..	13.98	15.07		Advantan	CS
8055Y *NP*	Ointment 1 mg per g (0.1%), 15 g	‡1	..	..	13.98	15.07		Advantan	CS
8128T *NP*	Fatty ointment 1 mg per g (0.1%), 15 g	‡1	..	..	13.98	15.07		Advantan	CS

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	METHYLPREDNISOLONE ACEPONATE								
	Restricted benefit								
	Eczema.								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8618N *NP*	Lotion 1 mg per g (0.1%), 20 g	‡1	..	..	14.65	15.74		Advantan	CS
	MOMETASONE FUROATE								
	Restricted benefit								
	Treatment of corticosteroid-responsive dermatoses.								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1913Q *NP*	Cream 1 mg per g (0.1%), 15 g	‡1	..	..	13.92	15.01	a	Novasone	FR
				[B]2.45	16.37	15.01	a	Elocon	MK
1915T *NP*	Ointment 1 mg per g (0.1%), 15 g	‡1	..	..	13.92	15.01	a	Novasone	FR
				[B]2.45	16.37	15.01	a	Elocon	MK
8043H *NP*	Lotion 1 mg per g (0.1% w/w), 30 mL	‡1	..	..	18.23	19.32	a	Novasone	FR
				[B]2.45	20.68	19.32	a	Elocon	MK

Anti-acne preparations

Anti-acne preparations for topical use

Retinoids for topical use in acne

	ADAPALENE with BENZOYL PEROXIDE								
	Restricted benefit								
	Acute treatment, in combination with an oral antibiotic, of severe acne vulgaris.								
8954G	Gel 1 mg-25 mg per g (0.1%-2.5%), 30 g	‡1	1	..	36.92	35.40		Epiduo	GA
	ADAPALENE with BENZOYL PEROXIDE								
	Restricted benefit								
	Maintenance treatment of severe acne vulgaris.								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8955H *NP*	Gel 1 mg-25 mg per g (0.1%-2.5%), 30 g	‡1	3	..	36.92	35.40		Epiduo	GA

Anti-acne preparations for systemic use

Retinoids for treatment of acne

	ISOTRETINOIN								
	Caution								
	This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.								
	Note								
	Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.								

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Authority required (STREAMLINED)								
	1354								
	Severe cystic acne not responsive to other therapy.								
2549E	Capsule 40 mg	30	3	..	91.02	35.40		Oratane	GM
2591J	Capsule 10 mg	60	3	..	66.56	35.40	[a]	APO-Isotretinoin	TX
							[a]	Oratane	GM
							[a]	Roaccutane	RO
							[a]	Rocta 10	QA
2592K	Capsule 20 mg	60	3	..	100.15	35.40	[a]	APO-Isotretinoin	TX
							[a]	GenRx Isotretinoin	GX
							[a]	Oratane	GM
							[a]	Rocta 20	QA
				[B]1.63	101.78	35.40	[a]	Roaccutane	RO

Other dermatological preparations

Other dermatological preparations

Agents for dermatitis, excluding corticosteroids

PIMECROLIMUS

Authority required

Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:
(i) perioral dermatitis;
(ii) periorbital dermatitis;
(iii) rosacea;
(iv) epidermal atrophy;
(v) dermal atrophy;
(vi) allergy to topical corticosteroids;
(vii) cataracts;
(viii) glaucoma;
(ix) raised intraocular pressure.

Authority required

Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy, and where more than 3 months have passed since the initial diagnosis of atopic dermatitis.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:
(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions.

Note

No applications for increased maximum quantities and/or repeats will be authorised. Only 1 authority application per 6 months, per patient, will be authorised.

8802G	Cream 10 mg per g (1%), 15 g	‡1	1	..	33.79	34.88	Elidel	HM

Other dermatologicals

DAPSONE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1272Y *NP*	Tablet 100 mg	100	1	..	113.84	35.40	Link Medical Products Pty Ltd	LM
8801F *NP*	Tablet 25 mg	100	1	..	100.58	35.40	Link Medical Products Pty Ltd	LM

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	IMIQUIMOD							
	Authority required Treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma (sBCC) in patients with normal immune function for whom surgical excision, cryotherapy, or curettage with diathermy are inappropriate and topical drug therapy is required. The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.							
	Note The patient or carer must be able to understand and administer the imiquimod dosing regimen. No applications for increased maximum quantities and/or repeats will be authorised. Treatment of recurrent (previously treated) lesions will not be authorised.							
2546B	Cream 50 mg per g (5%), 250 mg single use sachets, 12	1	1	..	159.95	35.40	Aldara	IA

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Genito urinary system and sex hormones

Other gynecologicals

Contraceptives for topical use
Intrauterine contraceptives

LEVONORGESTREL
Restricted benefit
Contraception;

Idiopathic menorrhagia where oral treatments are ineffective;

Idiopathic menorrhagia where oral treatments are contraindicated.

8633J *NP*	Intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours)	1	..	..	246.41	35.40		Mirena	BN

Other gynecologicals
Prolactine inhibitors

BROMOCRIPTINE MESYLATE
Restricted benefit
Prevention of the onset of lactation in the puerperium for medical reasons.

1444B *NP*	Tablet 2.5 mg (base)	30	..	..	18.92	20.01	[a]	Kripton 2.5	AF
							[a]	Parlodel	NV

BROMOCRIPTINE MESYLATE
Restricted benefit
Acromegaly;

Parkinson's disease;

Pathological hyperprolactinaemia where surgery is not indicated;

Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;

Pathological hyperprolactinaemia where radiotherapy is not indicated;

Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.

Note
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

1443Y	Tablet 2.5 mg (base)	60	5	..	31.42	32.51	[a]	Kripton 2.5	AF
				..	*31.42	32.51	[a]	Parlodel	NV
1445C	Capsule 10 mg (base)	100	5	..	148.46	35.40		Kripton 10	AF
1446D	Capsule 5 mg (base)	60	5	..	48.28	35.40		Kripton 5	AF

CABERGOLINE
Restricted benefit
Prevention of the onset of lactation in the puerperium for medical reasons.

8115D *NP*	Tablet 500 micrograms	2	..	..	23.72	24.81	[a]	Dostan	GM
							[a]	Dostinex	PF

CABERGOLINE
Authority required (STREAMLINED)
2659
Pathological hyperprolactinaemia where surgery is not indicated;

Genito urinary system and sex hormones

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	2660 Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution; ***2661*** Pathological hyperprolactinaemia where radiotherapy is not indicated; ***2662*** Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.								
8114C	Tablet 500 micrograms	8	5	..	65.07	35.40	[a]	Dostan	GM
							[a]	Dostinex	PF
							[a]	Tinexa	QA
	QUINAGOLIDE HYDROCHLORIDE **Authority required (STREAMLINED)** ***2659*** Pathological hyperprolactinaemia where surgery is not indicated; ***2660*** Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution; ***2661*** Pathological hyperprolactinaemia where radiotherapy is not indicated; ***2662*** Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.								
8822H	Tablet 75 micrograms (base)	30	5	..	54.79	35.40		Norprolac	FP
8860H	Pack containing 3 tablets 25 micrograms (base) and 3 tablets 50 micrograms (base)	‡1	..	..	11.47	12.56		Norprolac	FP

Sex hormones and modulators of the genital system

Hormonal contraceptives for systemic use

Progestogens and estrogens, fixed combinations

LEVONORGESTREL with ETHINYLOESTRADIOL

1394J *NP*	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	2	..	16.99	18.08	[b]	Monofeme 28	FZ
							[a]	Levlen ED	SY
				[B]13.55	30.54	18.08	[b]	Nordette 28	PF
				[B]13.59	30.58	18.08	[a]	Microgynon 30 ED	BN
1456P *NP*	Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets	4	2	..	16.99	18.08		Microgynon 50 ED	BN

NORETHISTERONE with ETHINYLOESTRADIOL

2774B *NP*	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	4	2	..	*16.46	17.55	[a]	Norimin 28 Day	FZ
				[B]7.68	*24.14	17.55	[a]	Brevinor	PF
2775C *NP*	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	2	..	*16.46	17.55	[a]	Norimin-1 28 Day	FZ
				[B]7.68	*24.14	17.55	[a]	Brevinor-1	PF

NORETHISTERONE with MESTRANOL

3179H *NP*	Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets	4	2	..	*16.46	17.55		Norinyl-1/28	PF

Progestogens and estrogens, sequential preparations

LEVONORGESTREL with ETHINYLOESTRADIOL

1392G *NP*	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	4	2	..	16.99	18.08	[b]	Trifeme 28	FZ
							[a]	Logynon ED	SY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
				[B]13.55	30.54	18.08	[b]	Triphasil 28	PF
				[B]13.59	30.58	18.08	[a]	Triquilar ED	BN
	NORETHISTERONE with ETHINYLOESTRADIOL								
2776D *NP*	Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets	4	2	..	*16.46	17.55		Improvil 28 Day	FZ

Progestogens

	ETONOGESTREL								
8487Q *NP*	Subcutaneous implant 68 mg	1	..	..	215.92	35.40		Implanon NXT	MK
	LEVONORGESTREL								
2913H *NP,MW*	Tablets 30 micrograms, 28	4	2	..	17.32	18.41		Microlut 28	BN
	MEDROXYPROGESTERONE ACETATE								
3118D *NP*	Injection 150 mg in 1 mL	1	1	..	21.29	22.38	[a]	Depo-Ralovera	FZ
				[B]3.20	24.49	22.38	[a]	Depo-Provera	PF
	NORETHISTERONE								
1967M *NP*	Tablets 350 micrograms, 28	4	2	..	*16.46	17.55	[a]	Locilan 28 Day	FZ
								Micronor	JC
				[B]3.88	*20.34	17.55	[a]	Noriday 28 Day	PF

Androgens

3-oxoandrosten (4) derivatives

TESTOSTERONE

Authority required

Androgen deficiency in males with established pituitary or testicular disorders;

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.

8098F	Subcutaneous implant 100 mg	6	..	..	*209.58	35.40		Merck Sharp & Dohme (Australia) Pty Ltd	MK
8099G	Subcutaneous implant 200 mg	3	..	..	*209.55	35.40		Merck Sharp & Dohme (Australia) Pty Ltd	MK
8460G	Transdermal patches 12.2 mg (releasing approximately 2.5 mg per 24 hours), 60	‡1	5	..	95.84	35.40		Androderm	HH
8619P	Transdermal patches 24.3 mg (releasing approximately 5 mg per 24 hours), 30	‡1	5	..	95.84	35.40		Androderm	HH
8830R	Transdermal gel 50 mg in 5 g sachet, 30	‡1	5	..	95.12	35.40		Testogel	BN

TESTOSTERONE ENANTHATE

Authority required

Androgen deficiency in males with established pituitary or testicular disorders;

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.							
2114G	Injection 250 mg in 1 mL	3	3	..	33.48	34.57	Primoteston Depot	BN

TESTOSTERONE UNDECANOATE

Authority required

Androgen deficiency in males with established pituitary or testicular disorders;

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.

2115H	Capsule 40 mg	60	5	..	37.53	35.40	Andriol Testocaps	MK
9004X	I.M. injection 1,000 mg in 4 mL	1	1	..	147.41	35.40	Reandron 1000	BN

Estrogens

Natural and semisynthetic estrogens, plain

OESTRADIOL

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

1743R *NP*	Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 8	‡1	5	..	17.09	18.18	Estraderm 25	NV
8125P *NP*	Transdermal patches 3.8 mg (releasing approximately 50 micrograms per 24 hours), 4	‡1	5	..	17.09	18.18	Climara 50	BN
8126Q *NP*	Transdermal patches 7.6 mg (releasing approximately 100 micrograms per 24 hours), 4	‡1	5	..	19.13	20.22	Climara 100	BN
8140K *NP*	Transdermal patches 1.5 mg (releasing approximately 50 micrograms per 24 hours), 8	‡1	5	..	17.09	18.18	Estraderm MX 50	NV
8286D *NP*	Transdermal gel 1 mg in 1 g sachet, 28	‡1	5	..	17.09	18.18	Sandrena	AS
8311K *NP*	Transdermal patches 750 micrograms (releasing approximately 25 micrograms per 24 hours), 8	‡1	5	..	17.09	18.18	Estraderm MX 25	NV
8312L *NP*	Transdermal patches 3 mg (releasing approximately 100 micrograms per 24 hours), 8	‡1	5	..	19.13	20.22	Estraderm MX 100	NV
8485N *NP*	Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 4	‡1	5	..	17.09	18.18	Climara 25	BN
8486P *NP*	Transdermal patches 5.7 mg (releasing approximately 75 micrograms per 24 hours), 4	‡1	5	..	19.13	20.22	Climara 75	BN
8761D *NP*	Transdermal patches 390 micrograms (releasing approximately 25 micrograms per 24 hours), 8	‡1	5	..	17.09	18.18	Estradot 25	NV
8762E *NP*	Transdermal patches 585 micrograms (releasing approximately 37.5 micrograms per 24 hours), 8	‡1	5	..	17.09	18.18	Estradot 37.5	NV
8763F *NP*	Transdermal patches 780 micrograms (releasing approximately 50 micrograms per 24 hours), 8	‡1	5	..	17.09	18.18	Estradot 50	NV
8764G *NP*	Transdermal patches 1.17 mg (releasing approximately 75 micrograms per 24 hours), 8	‡1	5	..	19.13	20.22	Estradot 75	NV
8765H *NP*	Transdermal patches 1.56 mg (releasing approximately 100 micrograms per 24 hours), 8	‡1	5	..	19.13	20.22	Estradot 100	NV

OESTRADIOL

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Genito urinary system and sex hormones

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
1742Q *NP*	Vaginal tablets 25 micrograms, 15	‡1	2	..	23.24	24.33		Vagifem	NO
8274L *NP*	Tablet 2 mg	56	2	..	13.55	14.64		Zumenon	AB
	OESTRADIOL VALERATE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1663M *NP*	Tablet 1 mg	56	2	..	11.68	12.77		Progynova	BN
1664N *NP*	Tablet 2 mg	56	2	..	13.90	14.99		Progynova	BN
	OESTRIOL **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1771F *NP*	Pessaries 500 micrograms, 15	‡1	2	..	21.26	22.35		Ovestin Ovula	MK
1781R *NP*	Vaginal cream 1 mg per g (0.1%), 15 g	‡1	1	..	19.09	20.18		Ovestin	MK

Progestogens

Pregnen (4) derivatives

MEDROXYPROGESTERONE ACETATE
Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2321E *NP*	Tablet 10 mg	30	2	..	15.30	16.39	[a]	Medroxyprogesterone Sandoz	SZ
							[a]	Ralovera	FZ
				[B]1.64	16.94	16.39	[a]	Provera	PF
2323G *NP*	Tablet 5 mg	56	2	..	14.69	15.78	[a]	Ralovera	FZ
				[B]1.64	16.33	15.78	[a]	Provera	PF

MEDROXYPROGESTERONE ACETATE
Restricted benefit
Endometriosis.

2722G	Tablet 10 mg	100	2	..	30.70	31.79	[a]	Ralovera	FZ
				[B]1.53	32.23	31.79	[a]	Provera	PF

Estren derivatives

NORETHISTERONE
Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2993M *NP*	Tablet 5 mg	30	2	..	31.96	33.05		Primolut N	BN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Progestogens and estrogens in combination							
	Progestogens and estrogens, combinations							
	OESTRADIOL with NORETHISTERONE ACETATE							
	Note							
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8427M *NP*	Transdermal patches 620 micrograms-2.7 mg (releasing approximately 50 micrograms-140 micrograms per 24 hours), 8	‡1	5	..	19.13	20.22	Estalis continuous 50/140	NV
8428N *NP*	Transdermal patches 510 micrograms-4.8 mg (releasing approximately 50 micrograms-250 micrograms per 24 hours), 8	‡1	5	..	19.13	20.22	Estalis continuous 50/250	NV
	Progestogens and estrogens, sequential preparations							
	OESTRADIOL and OESTRADIOL with DYDROGESTERONE							
	Note							
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8244X *NP*	Pack containing 14 tablets oestradiol 2 mg and 14 tablets oestradiol 2 mg with dydrogesterone 10 mg	‡1	5	..	18.76	19.85	Femoston 2/10	AB
	OESTRADIOL and OESTRADIOL with NORETHISTERONE ACETATE							
	Note							
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8425K *NP*	Pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 620 micrograms-2.7 mg (releasing approximately 50 micrograms-140 micrograms per 24 hours)	‡1	5	..	19.13	20.22	Estalis sequi 50/140	NV
8426L *NP*	Pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 510 micrograms-4.8 mg (releasing approximately 50 micrograms-250 micrograms per 24 hours)	‡1	5	..	19.13	20.22	Estalis sequi 50/250	NV
	Gonadotropins and other ovulation stimulants							
	Gonadotropins							
	FOLLITROPIN ALFA							
	Restricted benefit							
	Anovulatory infertility.							
	Note							
	Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.							
	Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.							
	Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.							
	Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Restricted benefit For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.							
8713N	Injection 300 i.u. in 0.5 mL multi-dose cartridge	3	5	..	*563.43	35.40	Gonal-f Pen	SG
8714P	Injection 450 i.u. in 0.75 mL multi-dose cartridge	3	5	..	*841.92	35.40	Gonal-f Pen	SG
8715Q	Injection 900 i.u. in 1.5 mL multi-dose cartridge	2	5	..	*1115.24	35.40	Gonal-f Pen	SG
	FOLLITROPIN BETA **Restricted benefit** Anovulatory infertility. **Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived. Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception. Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment. Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment. **Restricted benefit** For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.							
8565T	Solution for injection 300 i.u. in 0.36 mL multi-dose cartridge	3	5	..	*563.43	35.40	Puregon 300 IU/0.36 mL	MK
8566W	Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge	2	5	..	*749.08	35.40	Puregon 600 IU/0.72 mL	MK
8871X	Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge	2	5	..	*1115.22	35.40	Puregon 900 IU/1.08 mL	MK
	HUMAN CHORIONIC GONADOTROPHIN **Restricted benefit** Anovulatory infertility. **Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived. Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception. Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment. Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment. **Restricted benefit** For the treatment of infertility in males due to hypogonadotrophic hypogonadism; For the treatment of infertility in males associated with isolated luteinising hormone deficiency; For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation. **Restricted benefit** For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months.							
1581F	Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL	1	5	..	53.47	35.40	Pregnyl	MK

Ovulation stimulants, synthetic

CLOMIPHENE CITRATE

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.

Genito urinary system and sex hormones

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Restricted benefit Anovulatory infertility; Patients undergoing in-vitro fertilisation.								
1211R	Tablet 50 mg	10	5	..	34.51	35.40	a	Clomid	SW
							a	Serophene	SG

Antiandrogens

Antiandrogens, plain preparations

CYPROTERONE ACETATE
Authority required (STREAMLINED)
1230
Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation).

Caution
This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

1269T	Tablet 50 mg	20	5	..	50.65	35.40	a	Cyprohexal	SZ
							a	Cyprone	AF
							a	Cyprostat	SY
							a	GenRx Cyproterone Acetate	GX
							a	Procur	GM
				B 2.97	53.62	35.40	a	Androcur	BN

CYPROTERONE ACETATE
Authority required (STREAMLINED)
1014
Advanced carcinoma of the prostate;

1404
To reduce drive in sexual deviations in males.

1270W	Tablet 50 mg	100	5	..	*197.98	35.40	a	Cyprohexal	SZ
							a	Cyprone	AF
							a	Cyprostat	SY
							a	GenRx Cyproterone Acetate	GX
							a	Procur	GM
				B 3.12	*201.10	35.40	a	Androcur	BN
8019C	Tablet 100 mg	50	5	..	161.60	35.40	a	Cyprohexal	SZ
							a	Cyprostat-100	SY
							a	GenRx Cyproterone Acetate	GX
							a	Procur 100	GM
				B 1.56	163.16	35.40	a	Androcur-100	BN

Other sex hormones and modulators of the genital system

Antigonadotropins and similar agents

DANAZOL
Caution
Pregnancy must be excluded prior to administration of this drug.

Authority required (STREAMLINED)
1090
Endometriosis, visually proven;

1151
Hereditary angio-oedema;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	2639 Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information); ***2640*** Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information).								
1285P	Capsule 100 mg	100	5	..	58.58	35.40		Azol 100	AF
1287R	Capsule 200 mg	100	5	..	86.97	35.40		Azol 200	AF
	GESTRINONE **Authority required (STREAMLINED)** ***3652*** Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy may be prescribed).								
8015W	Capsule 2.5 mg	8	5	..	81.81	35.40		Dimetriose	SW

Selective estrogen receptor modulators

	RALOXIFENE HYDROCHLORIDE **Authority required (STREAMLINED)** ***2647*** Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. **Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
8363E *NP*	Tablet 60 mg	28	5	..	57.87	35.40		Evista	LY

Urologicals

Other urologicals, incl. antispasmodics

Urinary antispasmodics

	OXYBUTYNIN **Restricted benefit** Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin.								
9454N *NP*	Transdermal patches 36 mg (releasing approximately 3.9 mg per 24 hours), 8	‡1	5	..	35.23	35.40		Oxytrol	HH
	OXYBUTYNIN HYDROCHLORIDE **Restricted benefit** Detrusor overactivity.								
8039D *NP*	Tablet 5 mg	100	5	..	15.40	16.49	[a]	Ditropan	SW
							[a]	Oxybutynin Sandoz	SZ
							[a]	Oxybutynin Winthrop	WA
	PROPANTHELINE BROMIDE **Restricted benefit** Detrusor overactivity.								
1953T *NP*	Tablet 15 mg	200	5	..	*26.46	27.55		Pro-Banthine	QA

Genito urinary system and sex hormones

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Other urologicals							
	PHENOXYBENZAMINE HYDROCHLORIDE **Restricted benefit** Phaeochromocytoma; Neurogenic urinary retention. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1166J *NP*	Capsules 10 mg, 30	3	5	..	*204.90	35.40	Dibenyline	GH
1862B *NP*	Capsule 10 mg	100	5	..	67.36	35.40	Dibenyline	GH
9286R *NP*	Capsules 10 mg, 100	‡1	5	..	1164.47	35.40	Dibenzyline	BZ
	SODIUM BICARBONATE							
9470K *NP*	Capsule 840 mg	100	2	..	14.00	15.09	Sodibic	AS
	Drugs used in benign prostatic hypertrophy							
	Alpha-adrenoreceptor antagonists							
	DUTASTERIDE with TAMSULOSIN **Authority required (STREAMLINED)** ***3687*** Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5490Y *NP*	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	30	5	..	35.29	35.40	Duodart 500ug/400ug	GK
	Testosterone-5-alpha reductase inhibitors							
	DUTASTERIDE **Authority required (STREAMLINED)** ***3667*** Treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment is initiated by a urologist. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5468T *NP*	Capsule 500 micrograms	30	5	..	30.43	31.52	Avodart	GK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Systemic hormonal preparations, excl. sex hormones and insulins

Pituitary and hypothalamic hormones and analogues

Anterior pituitary lobe hormones and analogues

ACTH

TETRACOSACTRIN

2832C	Injection 1 mg in 1 mL	5	5	..	*71.27	35.40	Synacthen Depot 1 mg/1 mL	NV

Thyrotropin

THYROTROPIN ALFA
Authority required (STREAMLINED)
3193
Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease.

2700D	Powder for injection 0.9 mg, 2	1	..	..	1901.42	35.40	Thyrogen	GZ

Posterior pituitary lobe hormones

Vasopressin and analogues

DESMOPRESSIN ACETATE
Authority required (STREAMLINED)
1678
Cranial diabetes insipidus.

2129C	Intranasal solution 100 micrograms per mL, 2.5 mL	5	5	..	*161.17	35.40	Minirin	FP
8662X	Tablet 200 micrograms	90	5	..	*179.91	35.40	Minirin	FP
8711L	Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL	2	5	..	*161.04	35.40	Minirin Nasal Spray	FP

DESMOPRESSIN ACETATE
Authority required (STREAMLINED)
2641
Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm;

2642
Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

Note
Not to be used in preference to enuresis alarms.
Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note
Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

8663Y	Tablet 200 micrograms	30	5	..	64.25	35.40	Minirin	FP

NP

DESMOPRESSIN ACETATE
Authority required (STREAMLINED)
2641
Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm;

2642
Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

Systemic hormonal preparations, excl. sex hormones and insulins

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Not to be used in preference to enuresis alarms. Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.							
	Note Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.							
8975J *NP*	Wafer 240 micrograms (base)	30	5	..	115.94	35.40	Minirin Melt	FP
9398P *NP*	Wafer 120 micrograms (base)	30	5	..	70.85	35.40	Minirin Melt	FP
	DESMOPRESSIN ACETATE **Authority required (STREAMLINED)** ***2641*** Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm; ***2642*** Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated. **Note** Not to be used in preference to enuresis alarms. Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.							
8712M *NP*	Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL	‡1	5	..	83.73	35.40	Minirin Nasal Spray	FP

Hypothalamic hormones

Gonadotropin-releasing hormones

	NAFARELIN **Authority required** Initial treatment (up to 6 months) of visually proven endometriosis; Subsequent treatment (up to 6 months) of visually proven endometriosis, where 2 years or more have elapsed since the end of the previous course and where a recent bone density assessment has been made. The date of the assessment must be provided.							
2962X	Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses	‡1	5	..	95.51	35.40	Synarel	PF

Corticosteroids for systemic use

Corticosteroids for systemic use, plain

Mineralocorticoids

	FLUDROCORTISONE ACETATE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1433K *NP*	Tablet 100 micrograms	200	1	..	*46.50	35.40	Florinef	QA

Glucocorticoids

	BETAMETHASONE ACETATE with BETAMETHASONE SODIUM PHOSPHATE **Restricted benefit** Alopecia areata; For local intra-articular or peri-articular infiltration; Granulomata, dermal; Keloid; Lichen planus hypertrophic; Lichen simplex chronicus;							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Lupus erythematosus, chronic discoid;								
	Necrobiosis lipoidica;								
	Uveitis.								
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2694T *NP*	Injection 3 mg-3.9 mg (equivalent to 5.7 mg betamethasone) in 1 mL	5	..	..	25.00	26.09		Celestone Chronodose	MK
	CORTISONE ACETATE								
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1246N *NP*	Tablet 5 mg	50	4	..	15.30	16.39		Cortate	AS
1247P *NP*	Tablet 25 mg	60	4	..	17.74	18.83		Cortate	AS
	DEXAMETHASONE								
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1292B *NP*	Tablet 500 micrograms	30	4	..	8.84	9.93		Dexmethsone	AS
2507Y *NP*	Tablet 4 mg	30	4	..	12.40	13.49		Dexmethsone	AS
	DEXAMETHASONE SODIUM PHOSPHATE								
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1291Y *NP*	Injection equivalent to 8 mg dexamethasone phosphate in 2 mL	5	1	..	24.20	25.29	[a]	Dexmethsone	AS
							[a]	Hospira Pty Limited	HH
2509C *NP*	Injection equivalent to 4 mg dexamethasone phosphate in 1 mL	5	..	..	16.22	17.31	[a]	Dexmethsone	AS
							[a]	Hospira Pty Limited	HH
	HYDROCORTISONE								
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1499X *NP*	Tablet 4 mg	50	4	..	23.05	24.14		Hysone 4	AF
1500Y *NP*	Tablet 20 mg	60	4	..	30.16	31.25		Hysone 20	AF
	HYDROCORTISONE SODIUM SUCCINATE								
1501B *NP*	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	2	..	..	*16.52	17.61		Solu-Cortef	PF
3096Y *NP*	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	..	..	15.54	16.63		Solu-Cortef	PF

Systemic hormonal preparations, excl. sex hormones and insulins

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	HYDROCORTISONE SODIUM SUCCINATE								
	Restricted benefit								
	For use in a hospital.								
1510L *NP*	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	6	..	..	*36.72	35.40		Solu-Cortef	PF
1511M *NP*	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	6	..	..	*58.74	35.40		Solu-Cortef	PF
	METHYLPREDNISOLONE								
	Note								
	Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.								
2981X *NP*	Powder for injection 40 mg (as sodium succinate) with diluent	5	..	..	30.47	31.56	a	Solu-Medrol	PF
5263B *NP*	Powder for injection 40 mg (as sodium succinate)	5	..	..	30.47	31.56	a	Methylpred	AS
	METHYLPREDNISOLONE								
	Note								
	Pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) with diluent are equivalent for the purposes of substitution.								
5264C *NP*	Powder for injection 1 g (as sodium succinate)	1	..	..	79.69	35.40	a	Methylpred	AS
8834Y *NP*	Powder for injection 1 g (as sodium succinate) with diluent	1	..	..	79.69	35.40	a	Solu-Medrol	PF
	METHYLPREDNISOLONE ACETATE								
	Restricted benefit								
	For local intra-articular or peri-articular infiltration.								
1928L *NP*	Injection 40 mg in 1 mL	5	..	..	21.38	22.47	a	Depo-Nisolone	FZ
				[B]0.60	21.98	22.47	a	Depo-Medrol	PF
	PREDNISOLONE								
1916W *NP*	Tablet 25 mg	30	4	..	10.13	11.22		Panafcortelone	AS
								Solone	VT
1917X *NP*	Tablet 5 mg	60	4	..	8.48	9.57		Panafcortelone	AS
								Solone	VT
3152X *NP*	Tablet 1 mg	100	4	..	8.33	9.42	a	Predsolone	LN
				[B]0.44	8.77	9.42	a	Panafcortelone	AS
	PREDNISOLONE SODIUM PHOSPHATE								
8285C *NP*	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	‡1	5	..	14.70	15.79	a	PredMix	LN
				[B]1.77	16.47	15.79	a	Redipred	AS
	PREDNISONE								
1934T *NP*	Tablet 1 mg	100	4	..	8.86	9.95	a	Predsone	LN
				[B]0.61	9.47	9.95	a	Panafcort	AS
1935W *NP*	Tablet 5 mg	60	4	..	9.18	10.27		Panafcort	AS
								Sone	VT
1936X	Tablet 25 mg	30	4	..	11.41	12.50		Panafcort	AS

Systemic hormonal preparations, excl. sex hormones and insulins

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP								Sone	VT

TRIAMCINOLONE ACETONIDE

Restricted benefit

Alopecia areata;

For local intra-articular or peri-articular infiltration;

Granulomata, dermal;

Keloid;

Lichen planus hypertrophic;

Lichen simplex chronicus;

Lupus erythematosus, chronic discoid;

Necrobiosis lipoidica;

Psoriasis.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2990J *NP*	Injection 10 mg in 1 mL	5	..	..	25.00	26.09		Kenacort-A10	QA

Thyroid therapy

Thyroid preparations

Thyroid hormones

LIOTHYRONINE SODIUM

Authority required (STREAMLINED)

1219

Management of patients with thyroid cancer;

1858

Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium;

1859

Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium;

1182

Initiation of thyroid therapy in severely hypothyroid patients.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2318B *NP*	Tablet 20 micrograms	100	2	..	83.53	35.40		Tertroxin	QA

THYROXINE SODIUM

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2173J *NP*	Tablet equivalent to 200 micrograms anhydrous thyroxine sodium	200	1	..	27.01	28.10	a	Eutroxsig	FM
				[B]2.21	29.22	28.10	a	Oroxine	QA
2174K *NP*	Tablet equivalent to 50 micrograms anhydrous thyroxine sodium	200	1	..	23.37	24.46	a	Eutroxsig	FM
				[B]2.21	25.58	24.46	a	Oroxine	QA
2175L *NP*	Tablet equivalent to 100 micrograms anhydrous thyroxine sodium	200	1	..	23.98	25.07	a	Eutroxsig	FM
				[B]2.21	26.19	25.07	a	Oroxine	QA

Systemic hormonal preparations, excl. sex hormones and insulins

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
9287T *NP*	Tablet equivalent to 75 micrograms anhydrous thyroxine sodium	200	1	..	24.02	25.11	[a]	Eutroxsig	FM
				[B]2.27	26.29	25.11	[a]	Oroxine	QA

Antithyroid preparations

Thiouracils

PROPYLTHIOURACIL

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1955X *NP*	Tablet 50 mg	200	2	..	*49.64	35.40		PTU	PL

Sulfur-containing imidazole derivatives

CARBIMAZOLE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1153Q *NP*	Tablet 5 mg	200	2	..	*31.04	32.13		Neo-Mercazole	LM

Pancreatic hormones

Glycogenolytic hormones

Glycogenolytic hormones

GLUCAGON HYDROCHLORIDE

1449G *NP*	Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	1	..	45.63	35.40		GlucaGen Hypokit	NO

Calcium homeostasis

Parathyroid hormones and analogues

Parathyroid hormones and analogues

TERIPARATIDE

Note

Any queries concerning the arrangements to prescribe teriparatide may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe teriparatide should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who:
(a) has a bone mineral density (BMD) T-score of -3.0 or less; and
(b) has had 2 or more fractures due to minimal trauma; and
(c) has experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Systemic hormonal preparations, excl. sex hormones and insulins

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided at the time of application.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details of accepted toxicities including severity can be found on the Medicare Australia website at www.medicareaustralia.gov.au and must be provided at the time of application.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, disodium etidronate 200 mg with calcium carbonate 1.25 g per day, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Authority applications must be made in writing and must include:
Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed during the course of anti-resorptive therapy and the score of the qualifying BMD measurement.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Authority required
Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who was receiving treatment with teriparatide prior to 1 May 2009.

The authority application must be made in writing and the commencement date of treatment and the number of doses the patient has received of teriparatide must be provided with the application. The patient is eligible to receive a maximum of 18 months therapy of combined PBS-subsidised and non-PBS-subsidised therapy.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Authority required
Continuing treatment for severe established osteoporosis where the patient has previously been issued with an authority prescription for this drug.

Teriparatide must only be used for a lifetime maximum of 18 months therapy (18 pens). Up to a maximum of 18 pens will be reimbursed through the PBS.

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Note
Special Pricing Arrangements apply.

9411H	Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen	1	5	..	438.37	35.40	Forteo	LY

Anti-parathyroid agents
Calcitonin preparations

SALCATONIN

Note
The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer's packs. The pack size for both strengths is five ampoules.

Authority required (STREAMLINED)
3256
Symptomatic Paget disease of bone;

1412
Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2995P *NP*	Injection 50 i.u. in 1 mL	30	5	..	*207.66	35.40	Miacalcic 50	NV

Systemic hormonal preparations, excl. sex hormones and insulins

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
2997R *NP*	Injection 100 i.u. in 1 mL	15	5	..	*161.13	35.40	Miacalcic 100	NV

Other anti-parathyroid agents

CINACALCET

Authority required (STREAMLINED)

3673

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in iPTH concentrations after 6 months treatment;

3672

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L after 6 months treatment.

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Special Pricing Arrangements apply.

9157Y *NP*	Tablet 30 mg (as hydrochloride)	28	5	..	343.60	35.40	Sensipar	AN
9158B *NP*	Tablet 60 mg (as hydrochloride)	28	5	..	670.32	35.40	Sensipar	AN
9159C *NP*	Tablet 90 mg (as hydrochloride)	28	5	..	1002.27	35.40	Sensipar	AN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Antiinfectives for systemic use

Antibacterials for systemic use

Tetracyclines

Tetracyclines

DOXYCYCLINE

Note

Pharmaceutical benefits that have the form doxycycline tablet 100 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 100 mg (as monohydrate) are equivalent for the purposes of substitution.

2709N *NP*	Tablet 100 mg (as hydrochloride)	7	1	..	8.36	9.45	[a]	Doxsig	QA
							[a]	Doxy-100	GM
							[a]	Doxylin 100	AF
9105F *NP*	Tablet 100 mg (as monohydrate)	7	1	..	8.36	9.45	[a]	Chem mart Doxycycline	CH
							[a]	Doxyhexal	SZ
							[a]	GenRx Doxycycline	GX
							[a]	Terry White Chemists Doxycycline	TW

DOXYCYCLINE

2708M *NP*	Capsule 100 mg (as hydrochloride)	7	1	..	8.36	9.45	[a]	Mayne Pharma Doxycycline	YT
				[B]1.10	9.46	9.45	[a]	Doryx	YN

DOXYCYCLINE

Restricted benefit

Bronchiectasis in patients aged 8 years or older;

Chronic bronchitis in patients aged 8 years or older;

Severe acne.

Note

Pharmaceutical benefits that have the form doxycycline tablet 50 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 50 mg (as monohydrate) are equivalent for the purposes of substitution.

2711Q *NP*	Tablet 50 mg (as hydrochloride)	25	5	..	9.88	10.97	[a]	Doxy-50	GM
							[a]	Doxylin 50	AF
				[B]1.20	11.08	10.97	[a]	Vibra-Tabs	PF
9106G *NP*	Tablet 50 mg (as monohydrate)	25	5	..	9.88	10.97	[a]	Chem mart Doxycycline	CH
							[a]	Doxyhexal	SZ
							[a]	Frakas	QA
							[a]	GenRx Doxycycline	GX
							[a]	Terry White Chemists Doxycycline	TW

DOXYCYCLINE

Restricted benefit

Bronchiectasis in patients aged 8 years or older;

Chronic bronchitis in patients aged 8 years or older;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Severe acne.								
2707L *NP*	Capsule 50 mg (as hydrochloride)	25	5	..	9.88	10.97	a	Mayne Pharma Doxycycline	YT
				[B]1.24	11.12	10.97	a	Doryx	YN

DOXYCYCLINE
Restricted benefit
Pelvic inflammatory disease.

Note
Pharmaceutical benefits that have the form doxycycline tablet 100 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 100 mg (as monohydrate) are equivalent for the purposes of substitution.

2702F *NP*	Tablet 100 mg (as hydrochloride)	28	..	..	*14.18	15.27	a	Doxsig	QA
							a	Doxy-100	GM
							a	Doxylin 100	AF
9107H *NP*	Tablet 100 mg (as monohydrate)	28	..	..	*14.18	15.27	a	Chem mart Doxycycline	CH
							a	Doxyhexal	SZ
							a	GenRx Doxycycline	GX
							a	Terry White Chemists Doxycycline	TW

DOXYCYCLINE
Restricted benefit
Pelvic inflammatory disease.

2703G *NP*	Capsule 100 mg (as hydrochloride)	28	..	..	*14.18	15.27	a	Mayne Pharma Doxycycline	YT
				[B]4.40	*18.58	15.27	a	Doryx	YN

DOXYCYCLINE
Restricted benefit
Urethritis.

Note
Pharmaceutical benefits that have the form doxycycline tablet 100 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 100 mg (as monohydrate) are equivalent for the purposes of substitution.

2714W *NP*	Tablet 100 mg (as hydrochloride)	21	..	..	*12.24	13.33	a	Doxsig	QA
							a	Doxy-100	GM
							a	Doxylin 100	AF
9108J *NP*	Tablet 100 mg (as monohydrate)	21	..	..	*12.24	13.33	a	Chem mart Doxycycline	CH
							a	Doxyhexal	SZ
							a	Terry White Chemists Doxycycline	TW
				..	12.25	13.34	a	GenRx Doxycycline	GX

DOXYCYCLINE
Restricted benefit
Urethritis.

2715X *NP*	Capsule 100 mg (as hydrochloride)	21	..	..	12.22	13.31	a	Mayne Pharma Doxycycline	YT

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
				[B]1.97	14.19	13.31	[a]	Doryx	YN
	MINOCYCLINE								
	Caution								
	There are concerns about the incidence of benign intracranial hypertension associated with this drug.								
	Restricted benefit								
	Severe acne not responding to other tetracyclines.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
1616C *NP*	Tablet 50 mg	60	5	..	15.05	16.14	[a]	Akamin 50	AF
				[B]1.89	16.94	16.14	[a]	Minomycin-50	QA

Beta-lactam antibacterials, penicillins
Penicillins with extended spectrum

	AMOXYCILLIN								
1884E *NP,MW*	Capsule 250 mg	20	1	..	7.73	8.82	[a]	Alphamox 250	AF
							[a]	Amoxycillin-GA	GM
							[a]	Amoxycillin Ranbaxy	RA
							[a]	Amoxycillin Sandoz	SZ
							[a]	APO-Amoxycillin	TX
							[a]	Chem mart Amoxycillin	CH
							[a]	Cilamox	QA
							[a]	GenRx Amoxycillin	GX
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.88	8.61	8.82	[a]	Amoxil	GK
1886G *NP*	Powder for syrup 125 mg per 5 mL, 100 mL	‡1	1	..	#10.17	11.61	[a]	Alphamox 125	AF
							[a]	Amoxycillin Sandoz	SZ
							[a]	Bgramin	GM
							[a]	Chem mart Amoxycillin	CH
							[a]	GenRx Amoxycillin	GX
							[a]	Ranmoxy	RA
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.89	#11.06	11.61	[a]	Amoxil	GK
1887H *NP*	Powder for syrup 250 mg per 5 mL, 100 mL	‡1	1	..	#10.68	12.12	[a]	Alphamox 250	AF
							[a]	Amoxycillin Sandoz	SZ
							[a]	Bgramin	GM
							[a]	Chem mart Amoxycillin	CH
							[a]	Cilamox	QA
							[a]	GenRx Amoxycillin	GX
							[a]	Ranmoxy	RA
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.87	#11.55	12.12	[a]	Amoxil Forte	GK
1889K *NP,MW*	Capsule 500 mg	20	1	..	9.03	10.12	[a]	Alphamox 500	AF

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Amoxycillin-GA	GM
							[a]	Amoxycillin generichealth 500	GQ
							[a]	Amoxycillin Ranbaxy	RA
							[a]	Amoxycillin Sandoz	SZ
							[a]	APO-Amoxycillin	TX
							[a]	Chem mart Amoxycillin	CH
							[a]	Cilamox	QA
							[a]	GenRx Amoxycillin	GX
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.89	9.92	10.12	[a]	Amoxil	GK
8705E *NP*	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡1	1	..	#12.54	13.98		Maxamox	SZ
	AMOXYCILLIN **Restricted benefit** Acute exacerbations of chronic bronchitis.								
8581P *NP*	Tablet 1 g	14	1	..	9.11	10.20	[a]	Amoxycillin Sandoz	BG
				[B]0.73	9.84	10.20	[a]	Maxamox	SZ
	AMPICILLIN								
2390T *NP*	Powder for injection 500 mg	5	1	..	10.85	11.94	[a]	Austrapen	LN
							[a]	Ibimicyn	TS
2977Q *NP*	Powder for injection 1 g	5	1	..	13.69	14.78	[a]	Aspen Ampicyn	AS
							[a]	Austrapen	LN
							[a]	Ibimicyn	TS

Beta-lactamase sensitive penicillins

	BENZATHINE BENZYLPENICILLIN								
2267H *NP*	Injection 900 mg in 2.3 mL single use pre-filled syringe	10	..	..	293.11	35.40		Bicillin L-A	PF
	BENZYLPENICILLIN								
1775K *NP,MW*	Powder for injection 600 mg	10	1	..	*42.92	35.40		BenPen	CS
2647H *NP*	Powder for injection 3 g	10	..	..	*66.92	35.40		BenPen	CS
	PHENOXYMETHYLPENICILLIN								
1787C *NP*	Tablet 250 mg	50	..	..	*11.32	12.41		Abbocillin-VK Filmtab	QA
1789E *NP*	Capsule 250 mg	50	..	..	11.16	12.25	[a]	Cilicaine VK	FM
							[a]	Cilopen VK	GM
								LPV	VT
2965C *NP*	Capsule 500 mg	50	..	..	13.47	14.56	[a]	Cilicaine VK	FM
							[a]	Cilopen VK	GM
								LPV	VT

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
3028J *NP*	Tablet 500 mg	50	..	..	*13.66	14.75		Abbocillin-VK Filmtab	QA
8976K *NP*	Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL	2	1	..	*#16.76	18.20		Phenoxymethyl-penicillin-AFT	AE
8977L *NP*	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL	2	1	..	*#19.32	20.76		Phenoxymethyl-penicillin-AFT	AE
9143F *NP*	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	2	1	..	*21.60	22.69	a	Cilicaine V	FM
				[B]1.90	*23.50	22.69	a	Abbocillin-V	QA

PHENOXYMETHYLPENICILLIN
Restricted benefit
Prophylaxis of recurrent streptococcal infections (including rheumatic fever).

1703P *NP*	Tablet 250 mg	50	5	..	*11.32	12.41		Abbocillin-VK Filmtab	QA
1705R *NP*	Capsule 250 mg	50	5	..	11.16	12.25	a	Cilicaine VK	FM
							a	Cilopen VK	GM
								LPV	VT

PROCAINE PENICILLIN

1794K *NP*	Injection 1.5 g	5	..	..	92.22	35.40		Cilicaine	QA

Beta-lactamase resistant penicillins

DICLOXACILLIN
Restricted benefit
Serious staphylococcal infections.

8121K *NP,MW*	Capsule 250 mg	24	..	..	11.19	12.28	a	Dicloxsig	QA
							a	Distaph 250	AF
8122L *NP,MW*	Capsule 500 mg	24	..	..	16.41	17.50	a	Diclocil	BQ
							a	Dicloxsig	QA
							a	Distaph 500	AF

FLUCLOXACILLIN
Caution
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

1524F *NP*	Powder for injection 500 mg	5	..	..	12.76	13.85	a	Flubiclox	TS
							a	Flucil	AS
1525G *NP*	Powder for injection 1 g	5	1	..	16.33	17.42	a	Flubiclox	TS
							a	Flucil	AS
							a	Hospira Pty Limited	HH

FLUCLOXACILLIN
Caution
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit
Serious staphylococcal infections.

1526H *NP,MW*	Capsule 250 mg (as sodium)	24	..	..	11.19	12.28	a	Flopen	AS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Staphylex 250	AF
1527J *NP,MW*	Capsule 500 mg (as sodium)	24	..	..	16.41	17.50	[a]	Flopen	AS
							[a]	Staphylex 500	AF
9149M *NP*	Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL	‡1	..	..	#16.05	17.49		Flucil	LN
9150N *NP*	Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL	‡1	..	..	#19.58	21.02		Flucil	LN

Combinations of penicillins, incl. beta-lactamase inhibitors

AMOXYCILLIN with CLAVULANIC ACID

Caution

Hepatotoxicity has been reported with this drug.

Restricted benefit

Infections where resistance to amoxycillin is suspected;

Infections where resistance to amoxycillin is proven.

1891M *NP,MW*	Tablet 500 mg-125 mg	10	1	..	10.08	11.17	[a]	Amoxycillin/ Clavulanic Acid 500/125 generichealth	GQ
							[a]	APO-Amoxycillin/ Clavulanic Acid 500/125	TX
							[a]	Clamoxyl Duo	AL
							[a]	Curam Duo 500/125	SZ
							[a]	GA-Amclav 500/125	GM
							[a]	Moxiclav Duo 500/125	QA
				[B]1.57	11.65	11.17	[a]	Augmentin Duo	GK
1892N *NP*	Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL	‡1	1	..	#11.25	12.69	[a]	Clamoxyl	AL
							[a]	Curam	SZ
				[B]1.58	#12.83	12.69	[a]	Augmentin	GK
8254K *NP*	Tablet 875 mg-125 mg	10	1	..	11.63	12.72	[a]	Amoxycillin/ Clavulanic Acid 875/125 generichealth	GQ
							[a]	Chem mart Amoxycillin and Clavulanic Acid	CH
							[a]	Clamoxyl Duo forte	AL
							[a]	Clavycillin 875/125	CR
							[a]	Curam Duo Forte 875/125	SZ
							[a]	GA-Amclav Forte 875/125	GM
							[a]	GenRx Amoxycillin and Clavulanic Acid	GX
							[a]	Moxiclav Duo Forte 875/125	QA
							[a]	Terry White Chemists Amoxycillin and Clavulanic Acid	TW
				[B]1.56	13.19	12.72	[a]	Augmentin Duo forte	GK
8319W *NP*	Powder for syrup 400 mg-57 mg per 5 mL, 60 mL	‡1	1	..	#12.22	13.66	[a]	Clamoxyl Duo 400	AL
							[a]	Curam Duo	SZ
				[B]1.58	#13.80	13.66	[a]	Augmentin Duo	GK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								400	
	TICARCILLIN with CLAVULANIC ACID **Restricted benefit** Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent; Septicaemia, suspected; Septicaemia, proven. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2179Q *NP*	Powder for injection 3 g-100 mg (solvent required) (code 6884H applies to above item with approved solvent)	10	..	..	163.32	35.40		Timentin	GK

Other beta-lactam antibacterials
First-generation cephalosporins

	CEFALOTIN								
2964B *NP*	Powder for injection 1 g	10	1	..	26.25	27.34	a	Cefalotin Sandoz	SZ
							a	Hospira Pty Limited	HH
							a	Keflin Neutral	AS
	CEPHALEXIN								
3058Y *NP,MW*	Capsule 250 mg	20	1	..	7.92	9.01	a	Cefalexin Sandoz	SZ
							a	Cephalexin generichealth	GQ
							a	Cephalexin-PS	FZ
							a	Cephatrust 250	MI
							a	Chem mart Cephalexin	CH
							a	Cilex	GM
							a	GenRx Cephalexin	GX
							a	Ialex	LN
							a	Ibilex 250	AF
							a	Pharmacor Cephalexin 250	CR
							a	Rancef	RA
							a	Terry White Chemists Cephalexin	TW
				B2.03	9.95	9.01	a	Keflex	AS
3094W *NP*	Granules for syrup 125 mg per 5 mL, 100 mL	‡1	1	..	#10.78	12.22	a	APO-Cephalexin	TX
							a	Cefalexin Sandoz	SZ
							a	Chem mart Cephalexin	CH
							a	Cilex	GM
							a	GenRx Cephalexin	GX
							a	Ialex	LN
							a	Ibilex 125	AF
							a	Terry White Chemists Cephalexin	TW
				B2.20	#12.98	12.22	a	Keflex	AS
3095X	Granules for syrup 250 mg per 5 mL, 100 mL	‡1	1	..	#11.65	13.09	a	APO-Cephalexin	TX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP									
							[a]	Cefalexin Sandoz	SZ
							[a]	Chem mart Cephalexin	CH
							[a]	Cilex	GM
							[a]	GenRx Cephalexin	GX
							[a]	Ialex	LN
							[a]	Ibilex 250	AF
							[a]	Terry White Chemists Cephalexin	TW
				[B]2.70	#14.35	13.09	[a]	Keflex	AS
3119E	Capsule 500 mg	20	1	..	9.10	10.19	[a]	Cefalexin Sandoz	SZ
NP,MW									
							[a]	Cephabell	BF
							[a]	Cephalexin generichealth	GQ
							[a]	Cephalexin-PS	FZ
							[a]	Cephatrust 500	MI
							[a]	Chem mart Cephalexin	CH
							[a]	Cilex	GM
							[a]	GenRx Cephalexin	GX
							[a]	Ialex	LN
							[a]	Ibilex 500	AF
							[a]	Pharmacor Cephalexin 500	CR
							[a]	Rancef	RA
							[a]	Terry White Chemists Cephalexin	TW
				[B]2.73	11.83	10.19	[a]	Keflex	AS

CEPHAZOLIN

Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Septicaemia, suspected;

Septicaemia, proven.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1256D	Powder for injection 500 mg	10	..	..	*39.88	35.40	[a]	Cefazolin-AFT	AE
NP									
							[a]	Hospira Pty Limited	HH
1257E	Powder for injection 1 g	10	..	..	*56.92	35.40	[a]	Cefazolin-AFT	AE
NP									
							[a]	Hospira Pty Limited	HH
				..	56.93	35.40	[a]	Cefazolin Sandoz	SZ
							[a]	Cephazolin Alphapharm	AF
							[a]	Kefzol	AS
9326W	Powder for injection 2 g	10	..	..	*104.22	35.40	[a]	Cefazolin Sandoz	SZ
NP									
							[a]	Cephazolin Alphapharm	AF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	CEPHAZOLIN								
	Restricted benefit								
	Cellulitis.								
5477G	Powder for injection 500 mg	10	..	..	*39.88	35.40	a	Cefazolin-AFT	AE
NP							a	Hospira Pty Limited	HH
5478H	Powder for injection 1 g	10	..	..	*56.92	35.40	a	Cefazolin-AFT	AE
NP							a	Hospira Pty Limited	HH
				..	56.93	35.40	a	Cefazolin Sandoz	SZ
							a	Cephazolin Alphapharm	AF
							a	Kefzol	AS
5479J	Powder for injection 2 g	10	..	..	*104.22	35.40	a	Cefazolin Sandoz	SZ
NP							a	Cephazolin Alphapharm	AF

Second-generation cephalosporins

	CEFACLOR								
	Caution								
	Serum sickness-like reactions have been reported with this drug, especially in children.								
1169M	Tablet 375 mg (sustained release)	10	1	..	11.33	12.42	a	Cefaclor-GA	GN
							a	Cefaclor GH	GQ
							a	Chem mart Cefaclor CD	CH
							a	GenRx Cefaclor CD	GX
							a	Karlor CD	LN
							a	Keflor CD	AF
							a	Ozcef	RA
							a	Terry White Chemists Cefaclor CD	TW
				B3.93	15.26	12.42	a	Ceclor CD	AS
2460L	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡1	1	..	#12.45	13.89	a	Aclor 125	QA
							a	Cefaclor Sandoz	SZ
							a	Chem mart Cefaclor	CH
							a	GenRx Cefaclor	GX
							a	Keflor	AF
							a	Ozcef	RA
							a	Terry White Chemists Cefaclor	TW
				B3.16	#15.61	13.89	a	Ceclor	AS
2461M	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡1	1	..	#12.69	14.13	a	Aclor 250	QA
							a	Cefaclor Sandoz	SZ
							a	Chem mart Cefaclor	CH
							a	GenRx Cefaclor	GX
							a	Keflor	AF
							a	Ozcef	RA
							a	Terry White Chemists Cefaclor	TW
				B3.31	#16.00	14.13	a	Ceclor	AS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	CEFUROXIME AXETIL								
8292K	Tablet 250 mg (base)	14	1	..	18.62	19.71		Zinnat	GK

Third-generation cephalosporins

CEFOTAXIME
Restricted benefit
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Septicaemia, suspected;

Septicaemia, proven.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1085D *NP*	Powder for injection 1 g	10	..	..	*26.32	27.41	a	Cefotaxime Sandoz	SZ
				..	26.44	27.53	a	Hospira Pty Limited	HH
1086E *NP*	Powder for injection 2 g	10	..	..	*42.92	35.40	a	Cefotaxime Sandoz	SZ
				..	43.02	35.40	a	Hospira Pty Limited	HH

CEFTRIAXONE
Restricted benefit
Gonorrhoea.

9058R *NP*	Powder for injection 500 mg	1	..	..	10.25	11.34		Ceftriaxone ICP	PP

CEFTRIAXONE
Restricted benefit
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Septicaemia, suspected;

Septicaemia, proven.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1783W *NP*	Powder for injection 500 mg	5	..	..	*25.57	26.66		Ceftriaxone ICP	PP
1784X *NP*	Powder for injection 1 g	5	..	..	*36.32	35.40	a	Ceftriaxone ICP	PP
							a	Ceftriaxone Sandoz	SZ
							a	DBL Ceftriaxone	HH
							a	Rocephin	RO
				..	36.35	35.40	a	Max Pharma Pty Ltd	XF
1785Y *NP*	Powder for injection 2 g	5	..	..	*59.52	35.40	a	Ceftriaxone ICP	PP
							a	Ceftriaxone Sandoz	SZ
							a	DBL Ceftriaxone	HH
							a	Rocephin	RO

Fourth-generation cephalosporins

CEFEPIME
Authority required
Treatment of febrile neutropenia.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8315P *NP*	Powder for injection 1 g (as hydrochloride) (solvent required) (code 7079N applies to above item with approved solvent)	10	..	..	*161.62	35.40	[a]	DBL Cefepime	HH
							[a]	Maxipime	BQ
							[a]	Omegapharm Pty Ltd	OE
8316Q *NP*	Powder for injection 2 g (as hydrochloride) (solvent required) (code 7085X applies to above item with approved solvent)	10	..	..	*293.22	35.40	[a]	DBL Cefepime	HH
							[a]	Maxipime	BQ
							[a]	Omegapharm Pty Ltd	OE

Sulfonamides and trimethoprim

Trimethoprim and derivatives

TRIMETHOPRIM

2922T *NP*	Tablet 300 mg	7	1	..	8.38	9.47	[a]	Alprim	AF
				[B]1.89	10.27	9.47	[a]	Triprim	QA

Combinations of sulfonamides and trimethoprim, incl. derivatives

TRIMETHOPRIM with SULFAMETHOXAZOLE

Caution

There is an increased risk of severe adverse reactions with this combination in the elderly.

2951H *NP*	Tablet 160 mg-800 mg	10	1	..	9.24	10.33	[a]	Bactrim DS	RO
							[a]	Resprim Forte	AF
				[B]1.46	10.70	10.33	[a]	Septrin Forte	QA
3103H *NP*	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡1	1	..	8.93	10.02		Bactrim	RO
				[B]1.79	10.72	10.02		Septrin	QA

Macrolides, lincosamides and streptogramins

Macrolides

AZITHROMYCIN

Restricted benefit

Uncomplicated urethritis due to Chlamydia trachomatis;

Uncomplicated cervicitis due to Chlamydia trachomatis.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8200N *NP*	Tablet 500 mg (as dihydrate)	2	..	..	21.09	22.18	[a]	Azithromycin Sandoz	SZ
							[a]	Zithromax	PF
							[a]	Zitrocin	GM

AZITHROMYCIN

Restricted benefit

Trachoma.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8201P *NP*	Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL	‡1	..	..	#21.14	22.58		Zithromax	PF
8336R *NP*	Tablet 500 mg (as dihydrate)	2	2	..	21.09	22.18	[a]	Azithromycin Sandoz	SZ
							[a]	Zithromax	PF
							[a]	Zitrocin	GM
	CLARITHROMYCIN								
8318T *NP*	Tablet 250 mg	14	1	..	11.22	12.31	[a]	APO-Clarithromycin	TX
							[a]	Chem mart Clarithromycin	CH
							[a]	Clarac	GM
							[a]	Clarihexal	SZ
							[a]	Clarithro 250	QA
							[a]	GenRx Clarithromycin	GX
							[a]	Kalixocin	AF
							[a]	Terry White Chemists Clarithromycin	TW
				[B]1.50	12.72	12.31	[a]	Klacid	AB
	CLARITHROMYCIN **Restricted benefit** Bordetella pertussis; Atypical mycobacterial infections.								
9192T *NP*	Powder for oral liquid 250 mg per 5 mL, 50 mL	‡1	..	..	#30.67	32.11		Klacid	AB
	ERYTHROMYCIN								
1404X *NP*	Capsule 250 mg	25	1	..	10.69	11.78	[a]	Mayne Pharma Erythromycin	YT
				[B]2.38	13.07	11.78	[a]	Eryc	YN
	ERYTHROMYCIN ETHYL SUCCINATE								
2424N *NP*	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	‡1	1	..	#14.52	15.96	[a]	E-Mycin 200	AF
				[B]2.71	#17.23	15.96	[a]	E.E.S. 200	LM
2428T *NP*	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	‡1	1	..	#16.03	17.47	[a]	E-Mycin 400	AF
				[B]2.73	#18.76	17.47	[a]	E.E.S. Granules	LM
2750R *NP*	Tablet 400 mg (base)	25	1	..	10.69	11.78	[a]	E-Mycin	AF
				[B]2.66	13.35	11.78	[a]	E.E.S. 400 Filmtab	LM
	ERYTHROMYCIN LACTOBIONATE								
1397M *NP*	Powder for I.V. infusion 1 g (base)	5	..	..	*98.62	35.40		Erythrocin-I.V.	LM
	ROXITHROMYCIN								
1760P *NP*	Tablet 150 mg	10	1	..	9.76	10.85	[a]	APO-Roxithromycin	TX
							[a]	Biaxsig	AV
							[a]	Chem mart Roxithromycin	CH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Roxar 150	QA
							[a]	Roximycin	AF
							[a]	Roxithromycin-GA	GM
							[a]	Roxithromycin Sandoz	SZ
							[a]	Terry White Chemists Roxithromycin	TW
				[B]1.71	11.47	10.85	[a]	Rulide	SW
8016X *NP*	Tablet 300 mg	5	1	..	9.76	10.85	[a]	APO-Roxithromycin	TX
							[a]	Biaxsig	AV
							[a]	Chem mart Roxithromycin	CH
							[a]	Roxar 300	QA
							[a]	Roximycin	AF
							[a]	Roxithromycin-GA	GM
							[a]	Roxithromycin Sandoz	SZ
							[a]	Terry White Chemists Roxithromycin	TW
				[B]1.71	11.47	10.85	[a]	Rulide	SW
8129W *NP*	Tablet for oral suspension 50 mg	10	1	..	12.89	13.98		Rulide D	SW

Lincosamides

CLINDAMYCIN
Restricted benefit
Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.

3138E *NP,MW*	Capsule 150 mg	24	..	..	19.75	20.84	[a]	Cleocin	FZ
				[B]1.37	21.12	20.84	[a]	Dalacin C	PF

LINCOMYCIN

2530E *NP,MW*	Injection 600 mg in 2 mL	5	..	..	33.74	34.83		Lincocin	PF

Aminoglycoside antibacterials

Other aminoglycosides

GENTAMICIN SULFATE

2824P *NP*	Injection 80 mg (base) in 2 mL	10	1	..	19.67	20.76		Pfizer Australia Pty Ltd	PF

TOBRAMYCIN
Authority required (STREAMLINED)
3842
Management of a proven Pseudomonas aeruginosa infection in a patient with cystic fibrosis.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Note
Special Pricing Arrangements apply.

5442K	Solution for inhalation 300 mg in 5 mL	56	2	..	2137.36	35.40		Tobi	NV

TOBRAMYCIN SULFATE
Restricted benefit
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Septicaemia, suspected;								
	Septicaemia, proven.								
1356J *NP*	Injection 80 mg (base) in 2 mL	10	1	..	*65.02	35.40		Hospira Pty Limited	HH
8872Y *NP*	Injection 80 mg (base) in 2 mL (without preservative)	10	1	..	*65.02	35.40		Pfizer Australia Pty Ltd	PF

TOBRAMYCIN SULFATE
Restricted benefit
Systemic treatment of Pseudomonas aeruginosa infection in a patient with cystic fibrosis.

9480Y *NP*	Injection 500 mg (base) in 5 mL (without preservative)	10	1	..	357.37	35.40		Tobra-Day	PL

Quinolone antibacterials
Fluoroquinolones

CIPROFLOXACIN
Authority required
Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients;

Bacterial gastroenteritis in severely immunocompromised patients;

Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials;

Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials;

Gonorrhoea.

1208N *NP*	Tablet 250 mg	14	..	..	17.23	18.32	[a]	C-Flox 250	AL
							[a]	Cifran	RA
							[a]	Ciprofloxacin-DRLA	RZ
							[a]	Ciprofloxacin Sandoz	SZ
							[a]	Ciprol 250	QA
							[a]	GenRx Ciprofloxacin	GX
							[a]	Profloxin	HX
				[B]0.79	18.02	18.32	[a]	Ciproxin 250	BN

CIPROFLOXACIN
Authority required
Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients;

Bacterial gastroenteritis in severely immunocompromised patients;

Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials;

Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials.

1209P *NP*	Tablet 500 mg	14	..	..	27.56	28.65	[a]	C-Flox 500	AL
							[a]	Cifran	RA
							[a]	Ciprofloxacin 500	CR
							[a]	Ciprofloxacin-BW	BF
							[a]	Ciprofloxacin-DRLA	RZ
							[a]	Ciprofloxacin-GA	GM
							[a]	Ciprofloxacin-PS	FZ
							[a]	Ciprofloxacin Sandoz	SZ
							[a]	Ciprol 500	QA

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	GenRx Ciprofloxacin	GX
				[B]0.79	28.35	28.65	[a]	Ciproxin 500	BN
1210Q *NP*	Tablet 750 mg	14	..	..	38.28	35.40	[a]	C-Flox 750	AL
							[a]	Cifran	RA
							[a]	Ciprofloxacin 750	CR
							[a]	Ciprofloxacin-BW	BF
							[a]	Ciprofloxacin-DRLA	RZ
							[a]	Ciprofloxacin-GA	GM
							[a]	Ciprofloxacin-PS	FZ
							[a]	Ciprofloxacin Sandoz	SZ
							[a]	Ciprol 750	QA
							[a]	GenRx Ciprofloxacin	GX
				[B]0.78	39.06	35.40	[a]	Ciproxin 750	BN
	NORFLOXACIN **Authority required** Acute bacterial enterocolitis; Complicated urinary tract infection.								
3010K *NP*	Tablet 400 mg	14	1	..	13.75	14.84	[a]	Chem mart Norfloxacin	CH
							[a]	GenRx Norfloxacin	GX
							[a]	Norfloxacin-GA	GM
							[a]	Norfloxacin Sandoz	SZ
							[a]	Nufloxib	AF
							[a]	Roxin	QA
							[a]	Terry White Chemists Norfloxacin	TW
				[B]2.66	16.41	14.84	[a]	Noroxin	MK

Other antibacterials

Glycopeptide antibacterials

VANCOMYCIN
Restricted benefit
Prophylaxis of endocarditis in patients hypersensitive to penicillin.

2269K	Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)	1	..	..	16.52	17.61	[a]	Hospira Pty Limited	HH
							[a]	Vancomycin Alphapharm	AF
							[a]	Vancomycin Sandoz	SZ
							[a]	Vycin IV	WQ
3130R	Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)	2	..	..	*16.52	17.61	[a]	Hospira Pty Limited	HH
							[a]	Vancocin CP	AS
							[a]	Vancomycin Alphapharm	AF
							[a]	Vancomycin Sandoz	SZ
							[a]	Vycin IV	WQ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	VANCOMYCIN								
	Restricted benefit								
	Endophthalmitis;								
	Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic.								
2270L	Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)	3	..	..	*36.72	35.40	[a]	Hospira Pty Limited	HH
							[a]	Vancomycin Alphapharm	AF
							[a]	Vancomycin Sandoz	SZ
							[a]	Vycin IV	WQ
3131T	Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)	5	..	..	*31.67	32.76	[a]	Hospira Pty Limited	HH
							[a]	Vancocin CP	AS
							[a]	Vancomycin Alphapharm	AF
							[a]	Vancomycin Sandoz	SZ
							[a]	Vycin IV	WQ
	Steroid antibacterials								
	FUSIDIC ACID								
	Restricted benefit								
	For use in combination with another antibiotic in the treatment of proven serious staphylococcal infections.								
2312Q	Tablet (sodium salt) 250 mg	36	1	..	90.89	35.40		Fucidin	CS
	Imidazole derivatives								
	METRONIDAZOLE								
1636D *NP*	Tablet 200 mg	21	1	..	7.88	8.97	[a]	Metrogyl 200	AF
							[a]	Metronide 200	AV
				[B]2.30	10.18	8.97	[a]	Flagyl	SW
1642K *NP*	Suppositories 500 mg, 10	‡1	..	..	23.16	24.25		Flagyl	SW
	METRONIDAZOLE								
	Restricted benefit								
	Treatment of anaerobic infections.								
1621H *NP*	Tablet 400 mg	21	1	..	9.85	10.94	[a]	Metrogyl 400	AF
							[a]	Metronide 400	AV
				[B]2.30	12.15	10.94	[a]	Flagyl	SW
	METRONIDAZOLE								
	Restricted benefit								
	Prophylaxis in large bowel surgery;								
	Treatment, in a hospital, of acute anaerobic sepsis.								
1638F *NP*	I.V. infusion 500 mg in 100 mL	5	1	..	*30.67	31.76	[a]	Baxter Healthcare Pty Ltd	BX
				..	*31.70	32.79	[a]	DBL Metronidazole Intravenous Infusion	HH
	METRONIDAZOLE BENZOATE								
1630T	Oral suspension 320 mg per 5 mL (equivalent to	‡1	..	..	18.82	19.91		Flagyl S	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP	200 mg metronidazole in 5 mL), 100 mL								
	TINIDAZOLE								
1465D	Tablet 500 mg	4	..	..	10.79	11.88	a	Simplotan	FZ
NP									
				[B]2.42	13.21	11.88	a	Fasigyn	PF

Nitrofuran derivatives

NITROFURANTOIN

Caution

Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

1692C	Capsule 50 mg	30	1	..	20.38	21.47		Macrodantin	PF
NP,MW									
1693D	Capsule 100 mg	30	1	..	26.26	27.35		Macrodantin	PF
NP,MW									

Other antibacterials

HEXAMINE HIPPURATE

3124K	Tablet 1 g	100	5	..	43.25	35.40		Hiprex	IA
NP									

Antimycotics for systemic use

Antimycotics for systemic use

Imidazole derivatives

KETOCONAZOLE

Authority required (STREAMLINED)

3606

Symptomatic genital candidiasis recurring after treatment of at least 2 episodes with topical therapy.

Caution

Hepatotoxicity has been reported with ketoconazole.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1573T	Tablet 200 mg	10	..	..	19.79	20.88		Nizoral	JC
NP									

KETOCONAZOLE

Authority required (STREAMLINED)

3604

Oral candidiasis in severely immunocompromised persons where topical therapy has failed;

3605

Systemic or deep mycoses where other forms of therapy have failed.

Caution

Hepatotoxicity has been reported with ketoconazole.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1572R	Tablet 200 mg	30	5	..	42.17	35.40		Nizoral	JC
NP									

Triazole derivatives

FLUCONAZOLE

Authority required (STREAMLINED)

3615

Treatment of cryptococcal meningitis;

3616

Maintenance therapy in patients with cryptococcal meningitis and immunosuppression;

3613

Treatment of oropharyngeal candidiasis in immunosuppressed patients;

3614

Treatment of oesophageal candidiasis in immunosuppressed patients;

3617

Prophylaxis of oropharyngeal candidiasis in immunosuppressed patients;

3618

Treatment of serious and life-threatening candida infections.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
1471K *NP*	Capsule 50 mg	28	5	..	41.41	35.40	a	Diflucan	PF
							a	Dizole 50	AF
							a	Fluconazole Sandoz	SZ
							a	Ozole	RA
1472L *NP*	Capsule 100 mg	28	5	..	71.75	35.40	a	Diflucan	PF
							a	Dizole 100	AF
							a	Fluconazole Sandoz	SZ
							a	Ozole	RA
1473M *NP*	Solution for I.V. infusion 100 mg in 50 mL	7	..	..	*117.23	35.40	a	Diflucan	PF
							a	Fluconazole-Claris	AE
							a	Fluconazole Hexal	HX
							a	Fluconazole Sandoz	SZ
1474N *NP*	Solution for I.V. infusion 200 mg in 100 mL	7	..	..	*213.97	35.40	a	Baxter Healthcare Pty Ltd	BX
							a	Diflucan	PF
							a	Fluconazole-Claris	AE
							a	Fluconazole Hexal	HX
							a	Fluconazole Sandoz	SZ
1475P *NP*	Capsule 200 mg	28	5	..	133.69	35.40	a	APO-Fluconazole	TX
							a	Diflucan	PF
							a	Dizole 200	AF
							a	Fluconazole Sandoz	SZ
							a	Fluzole 200	QA
							a	Ozole	RA
1757L *NP*	Solution for I.V. infusion 400 mg in 200 mL	1	..	..	53.53	35.40		Baxter Healthcare Pty Ltd	BX

FLUCONAZOLE

Authority required

Treatment of cryptococcal meningitis in a patient unable to take a solid dose form of fluconazole;

Maintenance therapy in a patient with cryptococcal meningitis and immunosuppression unable to take a solid dose form of fluconazole;

Treatment of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole;

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Treatment of oesophageal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole;							
	Prophylaxis of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole;							
	Treatment of serious and life-threatening candida infections in a patient unable to take a solid dose form of fluconazole.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5446P *NP*	Powder for oral suspension 50 mg in 5 mL, 35 mL	1	..	..	#57.85	35.40	Diflucan	PF
	ITRACONAZOLE **Authority required (STREAMLINED)** ***3607*** Systemic aspergillosis;							
	3608 Systemic sporotrichosis;							
	3609 Systemic histoplasmosis;							
	3610 Treatment and maintenance therapy in patients with AIDS who have disseminated pulmonary histoplasmosis infection;							
	3612 Treatment and maintenance therapy in patients with AIDS who have chronic pulmonary histoplasmosis infection;							
	3613 Treatment of oropharyngeal candidiasis in immunosuppressed patients;							
	3614 Treatment of oesophageal candidiasis in immunosuppressed patients.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8196J *NP*	Capsule 100 mg	60	5	..	246.79	35.40	Sporanox	JC
	POSACONAZOLE **Authority required** Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy;							
	Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy.							
	Authority required Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows: (1) Neutropenia Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome. Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre. Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia. (2) Graft versus host disease (GVHD) Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant. No more than 6 months therapy per episode will be PBS-subsidised.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
	Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.							

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
9360P *NP*	Oral suspension 40 mg per mL, 105 mL	1	..	..	733.26	35.40	Noxafil	MK

VORICONAZOLE

Authority required

For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients;

For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species;

For the treatment and maintenance therapy of serious Candida infections where:
(a) the causative species is not susceptible to fluconazole; or

(b) treatment with fluconazole has failed; or

(c) treatment with fluconazole is not tolerated;

For the treatment and maintenance therapy of other serious invasive mycosis.

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9363T *NP*	Tablet 50 mg	56	2	..	700.87	35.40	Vfend	PF
9364W *NP*	Tablet 200 mg	56	2	..	2631.08	35.40	Vfend	PF

VORICONAZOLE

Authority required

For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients;

For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species;

For the treatment and maintenance therapy of serious Candida infections where:
(a) the causative species is not susceptible to fluconazole; or

(b) treatment with fluconazole has failed; or

(c) treatment with fluconazole is not tolerated;

For the treatment and maintenance therapy of other serious invasive mycosis.

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

9452L *NP*	Powder for oral suspension 40 mg per mL, 70 mL	1	..	..	#703.45	35.40	Vfend	PF

Antimycobacterials

Drugs for treatment of tuberculosis

Hydrazides

ISONIAZID

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1554T *NP*	Tablet 100 mg	100	2	..	21.49	22.58	Fawns and McAllan Proprietary Limited	FM

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Drugs for treatment of lepra								
	Drugs for treatment of lepra								
	DAPSONE								
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1272Y *NP*	Tablet 100 mg	100	1	..	113.84	35.40		Link Medical Products Pty Ltd	LM
8801F *NP*	Tablet 25 mg	100	1	..	100.58	35.40		Link Medical Products Pty Ltd	LM
	RIFAMPICIN								
	Authority required								
	Leprosy in adults.								
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1982H *NP*	Capsule 150 mg	100	..	..	49.88	35.40		Rimycin 150	AF
1983J *NP*	Capsule 300 mg	100	..	..	71.06	35.40		Rimycin 300	AF
	RIFAMPICIN								
	Restricted benefit								
	Prophylaxis of meningococcal disease in close contacts and carriers;								
	Prophylactic treatment of contacts of patients with Haemophilus influenzae type B.								
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1981G *NP*	Capsule 150 mg	10	..	..	44.89	35.40		Rimycin 150	AF
1984K *NP*	Capsule 300 mg	10	..	..	25.15	26.24		Rimycin 300	AF
8025J *NP*	Syrup 100 mg per 5 mL, 60 mL	‡1	..	..	28.57	29.66		Rifadin	SW

Antivirals for systemic use

Direct acting antivirals

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

	ACICLOVIR								
	Authority required (STREAMLINED)								
	3632								
	Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.								
	Note								
	Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
1003T *NP*	Tablet 200 mg	50	..	..	66.38	35.40	[a]	GenRx Aciclovir	GX
				..	*66.40	35.40	[a]	Acihexal	SZ
							[a]	Acyclo-V 200	AF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							a	Lovir	GM
				B4.10	*70.50	35.40	a	Zovirax 200 mg	GK

ACICLOVIR

Authority required (STREAMLINED)

3633

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Note

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

1007B *NP*	Tablet 200 mg	90	5	..	116.12	35.40	a	Aciclovir 200	CR
							a	Aciclovir GH	GQ
							a	Acihexal	SZ
							a	Acyclo-V 200	AF
							a	Chem mart Aciclovir	CH
							a	GenRx Aciclovir	GX
							a	Lovir	GM
							a	Ozvir	RA
							a	Terry White Chemists Aciclovir	TW
				B3.06	119.18	35.40	a	Zovirax 200 mg	GK

ACICLOVIR

Authority required (STREAMLINED)

3622

Treatment of patients with herpes zoster within 72 hours of the onset of the rash;

3631

Herpes zoster ophthalmicus.

Note

Aciclovir is effective only if commenced within 72 hours of onset of rash.

Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

Note

No applications for repeats will be authorised.

1052J *NP*	Tablet 800 mg	35	..	..	139.32	35.40	a	Aciclovir 800	CR
							a	Acihexal	SZ
							a	Acyclo-V 800	AF
							a	GenRx Aciclovir	GX
				B1.49	140.81	35.40	a	Zovirax 800 mg	GK

ACICLOVIR

Authority required (STREAMLINED)

3630

Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre).

8234J *NP*	Tablet 800 mg	120	5	..	425.23	35.40	a	Acihexal	SZ
							a	Acyclo-V 800	AF

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	FAMCICLOVIR **Authority required (STREAMLINED)** ***3624*** Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment. **Note** Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.								
8092X *NP*	Tablet 125 mg	40	1	..	131.88	35.40	a	APO-Famciclovir	TX
							a	Ezovir	AF
							a	Famvir	NV
							a	Favic 125	QA
	FAMCICLOVIR **Authority required (STREAMLINED)** ***3624*** Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment. **Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.								
2274Q *NP*	Tablet 250 mg	20	1	..	131.88	35.40	a	APO-Famciclovir	TX
							a	Ezovir	AF
							a	Famciclovir Sandoz	SZ
							a	Famvir	NV
							a	Favic 250	QA
	FAMCICLOVIR **Authority required (STREAMLINED)** ***3622*** Treatment of patients with herpes zoster within 72 hours of the onset of the rash. **Note** Famciclovir is effective only if commenced within 72 hours of onset of rash. Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. **Note** No applications for repeats will be authorised.								
8002E *NP*	Tablet 250 mg	21	..	..	138.16	35.40	a	APO-Famciclovir	TX
							a	Ezovir	AF
							a	Famciclovir Sandoz	SZ
							a	Famvir	NV
							a	Favic 250	QA
	FAMCICLOVIR **Authority required (STREAMLINED)** ***3623*** Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment. **Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.								
8217L *NP*	Tablet 250 mg	56	5	..	343.76	35.40	a	APO-Famciclovir	TX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Ezovir	AF
							[a]	Famciclovir Sandoz	SZ
							[a]	Famvir	NV
							[a]	Favic 250	QA

FAMCICLOVIR

Authority required (STREAMLINED)

3625

Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash.

Note

Famciclovir is effective only if commenced within 72 hours of onset of rash.

Famciclovir 500 mg is not PBS-subsidised for chickenpox.
Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Note

No applications for repeats will be authorised.

8897G *NP*	Tablet 500 mg	30	..	..	194.60	35.40	[a]	APO-Famciclovir	TX
							[a]	Chem mart Famciclovir	CH
							[a]	Famvir	NV
							[a]	Favic 500	QA
							[a]	Terry White Chemists Famciclovir	TW

FAMCICLOVIR

Authority required (STREAMLINED)

3626

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Authority required (STREAMLINED)

3627

Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Authority required (STREAMLINED)

3628

Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 150 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment;

3629

Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and other opportunistic infections or AIDS defining tumours. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Note

Famciclovir 500 mg is not PBS-subsidised for chickenpox.
Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

8896F *NP*	Tablet 500 mg	56	5	..	343.76	35.40	[a]	APO-Famciclovir	TX
							[a]	Chem mart Famciclovir	CH
							[a]	Ezovir	AF
							[a]	Famvir	NV
							[a]	Favic 500	QA
							[a]	Terry White Chemists	TW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Famciclovir	
	VALACICLOVIR **Authority required (STREAMLINED)** ***3632*** Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment. **Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. **Note** No applications for increased maximum quantities and/or repeats will be authorised.								
8133C *NP*	Tablet 500 mg (as hydrochloride)	20	..	..	*105.78	35.40	a	APO-Valaciclovir	TX
							a	Chem mart Valaciclovir	CH
							a	Terry White Chemists Valaciclovir	TW
							a	Vaclovir	AF
							a	Valaciclovir GA	GN
							a	Valaciclovir Pfizer	FZ
							a	Valaciclovir Sandoz	SZ
							a	Valnir	QA
							a	Valtrex	GK
							a	Valvala	NV
							a	Zelitrex	GM
	VALACICLOVIR **Authority required (STREAMLINED)** ***3624*** Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment. **Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.								
8134D *NP*	Tablet 500 mg (as hydrochloride)	30	5	..	155.43	35.40	a	APO-Valaciclovir	TX
							a	Chem mart Valaciclovir	CH
							a	Shilova 500	DO
							a	Terry White Chemists Valaciclovir	TW
							a	Vaclovir	AF
							a	Valaciclovir Actavis 500	TA
							a	Valaciclovir GA	GN
							a	Valaciclovir generichealth	GQ
							a	Valaciclovir Pfizer	FZ
							a	Valaciclovir RBX	RA
							a	Valaciclovir Sandoz	SZ
							a	Valaciclovir SZ	HX
							a	Valacor 500	QR
							a	Valnir	QA
							a	Valtrex	GK
							a	Valvala	NV

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Zelitrex	GM

VALACICLOVIR

Authority required (STREAMLINED)

3623

Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Note

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

5480K *NP*	Tablet 500 mg (as hydrochloride)	30	5	..	155.43	35.40	[a]	APO-Valaciclovir	TX
							[a]	Chem mart Valaciclovir	CH
							[a]	Shilova 500	DO
							[a]	Terry White Chemists Valaciclovir	TW
							[a]	Vaclovir	AF
							[a]	Valaciclovir Actavis 500	TA
							[a]	Valaciclovir GA	GN
							[a]	Valaciclovir generichealth	GQ
							[a]	Valaciclovir Pfizer	FZ
							[a]	Valaciclovir RBX	RA
							[a]	Valaciclovir SZ	HX
							[a]	Valacor 500	QR
							[a]	Valnir	QA
							[a]	Valtrex	GK
							[a]	Zelitrex	GM

VALACICLOVIR

Authority required (STREAMLINED)

3622

Treatment of patients with herpes zoster within 72 hours of the onset of the rash;

3631

Herpes zoster ophthalmicus.

Note

Valaciclovir is effective only if commenced within 72 hours of onset of rash.

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note

No applications for repeats will be authorised.

8064K *NP*	Tablet 500 mg (as hydrochloride)	42	..	..	214.06	35.40	[a]	APO-Valaciclovir	TX
							[a]	Chem mart Valaciclovir	CH
							[a]	Terry White Chemists Valaciclovir	TW
							[a]	Vaclovir	AF
							[a]	Valaciclovir Actavis 500	TA
							[a]	Valaciclovir GA	GN
							[a]	Valaciclovir generichealth	GQ

Antiinfectives for systemic use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
						[a]	Valaciclovir Pfizer	FZ
						[a]	Valaciclovir RBX	RA
						[a]	Valaciclovir Sandoz	SZ
						[a]	Valacor 500	QR
						[a]	Valnir	QA
						[a]	Valtrex	GK
						[a]	Valvala	NV
						[a]	Zelitrex	GM

Vaccines

Bacterial vaccines

Pneumococcal vaccines

PNEUMOCOCCAL VACCINE, POLYVALENT
Restricted benefit
Splenectomised persons over 2 years of age;
Persons with Hodgkin's disease;
Persons at high risk of pneumococcal infections.

1903E *NP*	Injection 0.5 mL (23 valent)	1	..	..	46.13	35.40	Pneumovax 23	CS

Tetanus vaccines

DIPHTHERIA and TETANUS VACCINE, ADSORBED, DILUTED FOR ADULT USE
Note
For immunisation of adults and children aged greater than or equal to 8 years.

8783G *NP*	Injection 0.5 mL in pre-filled syringe	5	..	..	75.34	35.40	ADT Booster	CS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Antineoplastic and immunomodulating agents

Antineoplastic agents

Alkylating agents

Nitrogen mustard analogues

CHLORAMBUCIL

1163F	Tablet 2 mg	100	2	..	*137.98	35.40		Leukeran	AS

CYCLOPHOSPHAMIDE

1266P	Tablet 50 mg	50	2	..	31.29	32.38		Cycloblastin	PF

MELPHALAN

2547C	Tablet 2 mg	25	1	..	50.88	35.40		Alkeran	AS

Alkyl sulphonates

BUSULFAN

1128J	Tablet 2 mg	100	..	..	86.26	35.40		Myleran	AS

Nitrosoureas

CARMUSTINE

Restricted benefit

Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery.

Note

Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

8898H	Implants 7.7 mg, 8	‡1	..	..	17539.32	35.40		Gliadel	OA

Other alkylating agents

TEMOZOLOMIDE

Authority required

Glioblastoma multiforme concomitantly with radiotherapy.

Note

Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

Note

No applications for increased repeats will be authorised.

8819E	Capsule 5 mg	15	2	..	*176.10	35.40	[a]	Astromide	WQ
							[a]	Temizole 5	QA
							[a]	Temodal	MK
8820F	Capsule 20 mg	15	2	..	*478.08	35.40	[a]	Astromide	WQ
							[a]	Temizole 20	QA
							[a]	Temodal	MK
8821G	Capsule 100 mg	15	2	..	*2019.24	35.40	[a]	Astromide	WQ
							[a]	Temizole 100	QA
							[a]	Temodal	MK
9361Q	Capsule 140 mg	15	2	..	*2755.74	35.40	[a]	Astromide	WQ
							[a]	Temizole 140	QA
							[a]	Temodal	MK

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	TEMOZOLOMIDE								
	Authority required								
	Recurrence of anaplastic astrocytoma following standard therapy;								
	Recurrence of glioblastoma multiforme following standard therapy;								
	Glioblastoma multiforme following radiotherapy.								
8378Y	Capsule 5 mg	5	5	..	62.98	35.40	[a]	Astromide	WQ
							[a]	Temizole 5	QA
							[a]	Temodal	MK
8379B	Capsule 20 mg	5	5	..	172.71	35.40	[a]	Astromide	WQ
							[a]	Temizole 20	QA
							[a]	Temodal	MK
8380C	Capsule 100 mg	5	5	..	679.93	35.40	[a]	Astromide	WQ
							[a]	Temizole 100	QA
							[a]	Temodal	MK
8381D	Capsule 250 mg	5	5	..	1567.45	35.40	[a]	Astromide	WQ
							[a]	Temizole 250	QA
							[a]	Temodal	MK
9362R	Capsule 140 mg	5	5	..	935.25	35.40	[a]	Astromide	WQ
							[a]	Temizole 140	QA
							[a]	Temodal	MK

Antimetabolites

Folic acid analogues

	METHOTREXATE								
1622J	Tablet 2.5 mg	30	5	..	13.12	14.21	[a]	Hospira Pty Limited	HH
							[a]	Methoblastin	PF
2272N	Tablet 10 mg	15	3	..	21.84	22.93		Methoblastin	PF
2395C	Injection 50 mg in 2 mL	5	5	..	29.64	30.73	[a]	Hospira Pty Limited	HH
							[a]	Pfizer Australia Pty Ltd	PF
				..	*29.67	30.76	[a]	Methaccord	WQ
2396D	Injection 5 mg in 2 mL	5	..	..	30.19	31.28		Hospira Pty Limited	HH

METHOTREXATE
Restricted benefit
For patients requiring doses greater than 20 mg per week.

1623K	Tablet 10 mg	50	2	..	45.28	35.40		Methoblastin	PF

Purine analogues

FLUDARABINE PHOSPHATE
Authority required
B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:
(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and
(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry.

9184J	Tablet 10 mg	20	5	..	936.70	35.40		Fludara	GZ

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	MERCAPTOPURINE							
1598D	Tablet 50 mg	100	2	..	*251.94	35.40	Purinethol	AS
	THIOGUANINE							
1233X	Tablet 40 mg	25	1	..	198.66	35.40	Lanvis	AS

Pyrimidine analogues

CAPECITABINE
Authority required
Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline;

Advanced breast cancer where therapy with a taxane and/or an anthracycline is contraindicated;

Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy;

Treatment of advanced or metastatic colorectal cancer;

Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour either as:
(a) monotherapy; or
(b) in combination with oxaliplatin;

Advanced (Stage III or IV) oesophago-gastric cancer, previously untreated, in combination with a cisplatin-based regimen, in a patient with a WHO performance status of 2 or less.

Note
In the adjuvant setting, the recommended treatment duration is 24 weeks.
Capecitabine is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.
Capecitabine is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

8361C	Tablet 150 mg	60	2	..	123.93	35.40	Xeloda	RO
8362D	Tablet 500 mg	120	2	..	695.17	35.40	Xeloda	RO

Plant alkaloids and other natural products

Vinca alkaloids and analogues

VINORELBINE
Authority required
Locally advanced or metastatic non-small cell lung cancer.

9009E	Capsule 20 mg (as tartrate)	20	2	..	*1973.02	35.40	Navelbine	FB
9010F	Capsule 30 mg (as tartrate)	16	2	..	*2340.02	35.40	Navelbine	FB

Podophyllotoxin derivatives

ETOPOSIDE

1389D	Capsule 100 mg	10	..	..	390.73	35.40	Vepesid	BQ
1396L	Capsule 50 mg	20	..	..	444.94	35.40	Vepesid	BQ

Cytotoxic antibiotics and related substances

Anthracyclines and related substances

IDARUBICIN HYDROCHLORIDE
Restricted benefit
Acute myelogenous leukaemia.

2446R	Capsule 5 mg	3	..	..	*247.11	35.40	Zavedos	PF
2448W	Capsule 10 mg	3	..	..	*451.62	35.40	Zavedos	PF

Other antineoplastic agents

Protein kinase inhibitors

DASATINIB
Note
Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase who has failed an adequate trial of imatinib or nilotinib as first-line treatment.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:
— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or
— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and
(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and
(3) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or
(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment
From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment
Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

6. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

2478K	Tablet 20 mg	60	5	..	3095.45	35.40	Sprycel	BQ
2482P	Tablet 50 mg	60	5	..	5003.80	35.40	Sprycel	BQ
2485T	Tablet 70 mg	60	5	..	6160.19	35.40	Sprycel	BQ
9342Q	Tablet 100 mg	30	5	..	5003.80	35.40	Sprycel	BQ

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

DASATINIB

Note

Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
(4) a signed patient acknowledgement form.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or
(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib
From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.							
	3. Continuing treatment with dasatinib or nilotinib - first-line All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows: (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.							
	4. For imatinib mesylate, dasatinib and nilotinib During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.							
	5. Authority approval requirements. Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 6. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 7. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.							
1354G	Tablet 20 mg	60	5	..	3095.45	35.40	Sprycel	BQ
1381Q	Tablet 50 mg	60	5	..	5003.80	35.40	Sprycel	BQ
1415L	Tablet 70 mg	60	5	..	6160.19	35.40	Sprycel	BQ
1416M	Tablet 100 mg	30	5	..	5003.80	35.40	Sprycel	BQ

DASATINIB

Note

Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Failure of treatment is defined as either: (i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib; (ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib; (iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation. Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and (c) a signed patient acknowledgement; and (d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided. **Authority required** Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007 and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation. Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and (c) a signed patient acknowledgement; and (d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided. **Authority required** Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant. **Note** No applications for increased repeats will be authorised.							
9125G	Tablet 20 mg	60	2	..	3095.45	35.40	Sprycel	BQ
9126H	Tablet 50 mg	60	2	..	5003.80	35.40	Sprycel	BQ
9127J	Tablet 70 mg	60	2	..	6160.19	35.40	Sprycel	BQ
9343R	Tablet 100 mg	30	2	..	5003.80	35.40	Sprycel	BQ
	ERLOTINIB **Authority required** Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer with a WHO performance status of 3 or less, after prior treatment with platinum-based chemotherapy, where: (1) (a) disease progression has occurred following treatment with docetaxel or pemetrexed; or (b) treatment with docetaxel and pemetrexed is either contraindicated or cannot be tolerated; and (2) further cytotoxic chemotherapy is not appropriate. **Authority required** Continuing PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer who has previously been issued with an authority prescription for this drug and who does not have progressive disease. **Note** Special Pricing Arrangements apply.							
9166K	Tablet 25 mg (as hydrochloride)	30	3	..	794.19	35.40	Tarceva	RO

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
9167L	Tablet 100 mg (as hydrochloride)	30	3	..	2703.34	35.40	Tarceva	RO
9168M	Tablet 150 mg (as hydrochloride)	30	3	..	3309.66	35.40	Tarceva	RO

GEFITINIB

Note

Any queries concerning the arrangements to prescribe gefitinib may be directed to Medicare Australia on 1800 700 270.

Written applications for authority to prescribe gefitinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where:
(1) disease progression has occurred following treatment with at least 1 chemotherapy agent; and
(2) there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Gefitinib (Iressa) PBS Authority Application for Use in the Treatment of Locally Advanced or Metastatic Non-Small Cell Lung Cancer - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) details of the prior chemotherapy including the name(s) of drug(s) and date of the most recent treatment cycle; and
(4) details of the patient's WHO performance status; and
(5) a copy of the pathology report providing evidence of the presence of activating mutation(s) of the EGFR gene from an Approved Pathology Authority.

Authority required

Continuing PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where the patient has previously been issued with an authority prescription for gefitinib.

Applications for continuing treatment may be made in writing or on the telephone by contacting Medicare Australia on 1800 700 270.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8769M	Tablet 250 mg	30	1	..	3851.36	35.40	Iressa	AP

IMATINIB

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
(4) a signed patient acknowledgement form.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

First continuing applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) demonstration of a response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining requirements]; or
(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib
From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.
Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 6. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 7. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.							
9113P	Tablet 100 mg (as mesylate)	60	5	..	2004.98	35.40	Glivec	NV
9114Q	Tablet 400 mg (as mesylate)	30	5	..	3863.60	35.40	Glivec	NV

IMATINIB

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Authority required

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or
(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly.

Authority required

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or (2) Extramedullary involvement other than spleen and liver. Applications for authorisation must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement. **Authority required** Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of: (i) the accelerated phase of chronic myeloid leukaemia; or (ii) the blast phase of chronic myeloid leukaemia. **Note** No applications for increased repeats will be authorised.							
9115R	Tablet 100 mg (as mesylate)	60	2	..	2004.98	35.40	Glivec	NV
9116T	Tablet 400 mg (as mesylate)	30	2	..	3863.60	35.40	Glivec	NV

IMATINIB

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Authority required

Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
(d) a signed patient acknowledgement.

Authority required

Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided);

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

and
(d) a signed patient acknowledgement.

Authority required
Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Imatinib mesylate is available with a lifetime maximum of 24 months for continuing treatment with imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Note
No applications for increased repeats will be authorised.

9123E	Tablet 100 mg (as mesylate)	60	2	..	2004.98	35.40	Glivec	NV
9124F	Tablet 400 mg (as mesylate)	30	2	..	3863.60	35.40	Glivec	NV

IMATINIB

Note
Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Authority required
Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.

Maximum dose: 800 mg per day.

(1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and
(2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and
(3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement.

Authority required
Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Maximum dose: 800 mg per day. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (c) a statement that the disease has not progressed on imatinib therapy. **Note** No applications for increased repeats will be authorised.							
9172R	Tablet 100 mg (as mesylate)	60	2	..	2004.98	35.40	Glivec	NV
9173T	Tablet 400 mg (as mesylate)	30	2	..	3863.60	35.40	Glivec	NV

IMATINIB

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Authority required

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRA fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) a signed patient acknowledgement.

Authority required

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
(d) a statement that the disease has not progressed on imatinib therapy.

Note

No applications for increased repeats will be authorised.

9174W	Tablet 100 mg (as mesylate)	60	2	..	2004.98	35.40	Glivec	NV
9175X	Tablet 400 mg (as mesylate)	30	2	..	3863.60	35.40	Glivec	NV

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	IMATINIB							
	Note							
	Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.							
	Written applications for authority to prescribe imatinib mesylate should be forwarded to:							
	Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
	For the following diseases, written authority is required at initiation and for continuation: Dermatofibrosarcoma protuberans; Hypereosinophilic syndrome; Chronic eosinophilic leukaemia; Myelodysplastic or myeloproliferative disorder; Aggressive systemic mastocytosis with eosinophilia.							
	Authority required							
	Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where: (1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and (2) the patient has previously failed an adequate trial of one or more of the following conventional therapies: — cytarabine; — etoposide; — hydroxyurea.							
	Maximum dose: 400 mg per day.							
	Applications for authorisation for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and (d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and (e) details of the prior therapy trialled and the response; and (f) a signed patient acknowledgement.							
	Authority required							
	Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.							
	Maximum dose: 400 mg per day.							
	Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (c) a copy of the full blood examination report which demonstrates a complete haematological response; and (d) a statement that the disease has not progressed on imatinib therapy.							
	Note							
	No applications for increased repeats will be authorised.							
9176Y	Tablet 100 mg (as mesylate)	60	2	..	2004.98	35.40	Glivec	NV
9177B	Tablet 400 mg (as mesylate)	30	2	..	3863.60	35.40	Glivec	NV
	IMATINIB							
	Note							
	Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.							

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Authority required
Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:
(1) there is confirmed evidence of the FIP1L1-PDGFRA fusion gene; and
(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:
— corticosteroids;
— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and
(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) details of prior treatment trialled and the response; and
(g) a signed patient acknowledgement.

Authority required
Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response; and
(d) a statement that the disease has not progressed on imatinib therapy.

Note
No applications for increased repeats will be authorised.

9178C	Tablet 100 mg (as mesylate)	60	2	..	2004.98	35.40	Glivec	NV
9179D	Tablet 400 mg (as mesylate)	30	2	..	3863.60	35.40	Glivec	NV

IMATINIB
Note
Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	For the following diseases, written authority is required at initiation and for continuation: Dermatofibrosarcoma protuberans; Hypereosinophilic syndrome; Chronic eosinophilic leukaemia; Myelodysplastic or myeloproliferative disorder; Aggressive systemic mastocytosis with eosinophilia. **Authority required** Initial PBS-subsidised treatment, for up to 3 months, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining. Patients must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and (ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and (iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided. **Authority required** Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for this drug. Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib. **Note** Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved. A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.) **Note** No applications for increased repeats will be authorised.							
9111M	Tablet 100 mg (as mesylate)	60	2	..	2004.98	35.40	Glivec	NV
9112N	Tablet 400 mg (as mesylate)	30	2	..	3863.60	35.40	Glivec	NV
	IMATINIB **Note** Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe imatinib mesylate should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 For the following diseases, written authority is required at initiation and for continuation: Dermatofibrosarcoma protuberans; Hypereosinophilic syndrome;							

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Chronic eosinophilic leukaemia; Myelodysplastic or myeloproliferative disorder; Aggressive systemic mastocytosis with eosinophilia. **Authority required** Adjuvant treatment of a patient at high risk of recurrence following complete resection of primary gastrointestinal stromal tumour (GIST) which has been histologically confirmed by the detection of CD117 on immunohistochemical staining, at a dose not exceeding 400 mg per day for a period of 12 months. High risk of recurrence is defined as: Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or Primary GIST greater than 10 cm with any mitotic rate; or Primary GIST with a mitotic count of greater than 10/50 HPF. (Prognosis definition based on the Australian and New Zealand consensus approach to best practice management, see Zalcberg et al. Asia-Pacific Journal of Clinical Oncology 2008: 4.4: 188-98.) Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and (ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application. **Authority required** Initial treatment of a patient who was receiving adjuvant imatinib mesylate for gastrointestinal stromal tumour (GIST) prior to 1 September 2011 and who meets the PBS eligibility criteria for adjuvant treatment with imatinib mesylate of a patient at high risk of recurrence following complete resection of primary GIST. The patient is eligible to receive sufficient imatinib at a dose of 400 mg per day to complete 12 months of combined PBS-subsidised and non-PBS-subsidised therapy. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and (ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented.							
5443L	Tablet 100 mg (as mesylate)	60	5	..	2004.98	35.40	Glivec	NV
5444M	Tablet 400 mg (as mesylate)	30	5	..	3863.60	35.40	Glivec	NV

LAPATINIB

Note

Any queries concerning the arrangements to prescribe lapatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab.

If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately.

Authority required

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer (equivalent to Stage IIIC or Stage IV) who has received prior therapy with a taxane, for at least 3 cycles, and whose disease has progressed despite treatment with trastuzumab for metastatic disease.

Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form;
(b) a pathology report demonstrating HER2 positivity has been demonstrated by in situ hybridisation (ISH);
(c) date of last treatment with a taxane and total number of cycles;
(d) a signed patient acknowledgment;
(e) dates of treatment with trastuzumab; and
(f) date of demonstration of progression whilst on treatment with trastuzumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Treatment with trastuzumab for metastatic disease is defined as trastuzumab administered alone or in combination with chemotherapy for at least 6 weeks at standard doses. If treatment with a taxane is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. **Authority required** Continuing treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who has previously received treatment with PBS-subsidised lapatinib and who does not have progressive disease. Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a statement from the prescribing doctor that the disease has not progressed. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
9148L	Tablet 250 mg (as ditosylate monohydrate)	140	2	..	*3387.46	35.40	Tykerb	GK
	NILOTINIB **Note** Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Applications for authority to prescribe nilotinib should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001. **Authority required** Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase who has failed an adequate trial of imatinib or dasatinib as first-line treatment. Failure of an adequate trial of imatinib or dasatinib is defined as: (i) Lack of response to initial imatinib or dasatinib therapy, defined as either: — failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or — failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or — failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR (ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR (iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR (iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following: (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or (3) Peripheral basophils greater than or equal to 20%; or (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and
(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and
(3) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or
(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment
From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment
Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.
Response criteria to initial treatment with dasatinib or nilotinib:

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 5. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.							
9171Q	Capsule 200 mg (as hydrochloride monohydrate)	120	5	..	*5872.14	35.40	Tasigna	NV

NILOTINIB

Note

Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
(4) a signed patient acknowledgement form.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or
(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib
From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.
Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

6. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

1309X	Capsule 150 mg (as hydrochloride monohydrate)	120	5	..	*4467.87	35.40	Tasigna	NV

SORAFENIB

Authority required

Initial treatment, as the sole PBS-subsidised agent, of advanced (BCLC Stage C) hepatocellular carcinoma in a patient with a WHO performance status of 2 or less and Child Pugh class A;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Continuing treatment, as the sole PBS-subsidised agent, of advanced hepatocellular carcinoma in a patient who has previously been treated with PBS-subsidised sorafenib and who does not have progressive disease.							
	Note Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization. Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Note Special Pricing Arrangements apply.							
9380Q	Tablet 200 mg (as tosylate)	120	2	..	*6457.08	35.40	Nexavar	BN
	SUNITINIB **Authority required** Initial treatment, as the sole PBS-subsidised therapy, of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient who meets the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group and has a WHO performance status of 2 or less.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
	Note Special Pricing Arrangements apply.							
9417P	Capsule 12.5 mg (as malate)	28	1	..	1834.20	35.40	Sutent	PF
9418Q	Capsule 25 mg (as malate)	28	1	..	3521.76	35.40	Sutent	PF
9419R	Capsule 50 mg (as malate)	28	1	..	6897.44	35.40	Sutent	PF
	SUNITINIB **Authority required** Continuing treatment beyond 3 months, as the sole PBS-subsidised therapy, of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient who has previously been issued with an authority prescription for sunitinib and who has stable or responding disease according to RECIST criteria.							
	Note RECIST Criteria is defined as follows: Complete response (CR) is disappearance of all target lesions. Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions. Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions. Stable disease (SD) is small changes that do not meet above criteria.							
	Authority required Initial treatment, as the sole PBS-subsidised therapy, of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient who was receiving treatment with sunitinib prior to 1 May 2009.							
	Note Special Pricing Arrangements apply.							
9420T	Capsule 12.5 mg (as malate)	28	3	..	1834.20	35.40	Sutent	PF
9421W	Capsule 25 mg (as malate)	28	3	..	3521.76	35.40	Sutent	PF
9422X	Capsule 50 mg (as malate)	28	3	..	6897.44	35.40	Sutent	PF
	SUNITINIB **Authority required** Initial PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate treatment due to resistance or intolerance.							
	Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and (3) a signed patient acknowledgement.							
	Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.							

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Any queries concerning the arrangements to prescribe sunitinib malate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority to prescribe sunitinib malate should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours. **Authority required** Continuing PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for sunitinib and who does not have progressive disease. Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients who have failed to respond or who are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib. Patients who have progressive disease on sunitinib are no longer eligible for PBS-subsidised sunitinib. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** Special Pricing Arrangements apply.							
9488J	Capsule 12.5 mg (as malate)	28	1	..	1834.20	35.40	Sutent	PF
9489K	Capsule 25 mg (as malate)	28	1	..	3521.76	35.40	Sutent	PF
9490L	Capsule 50 mg (as malate)	28	1	..	6897.44	35.40	Sutent	PF

Other antineoplastic agents

	HYDROXYUREA							
3093T	Capsule 500 mg	100	..	..	76.46	35.40	Hydrea	BQ

Endocrine therapy

Hormones and related agents

Progestogens

	MEDROXYPROGESTERONE ACETATE **Restricted benefit** Hormone-dependent advanced breast cancer.							
2728N	Tablet 500 mg	30	2	..	125.87	35.40	Provera	PF

	MEDROXYPROGESTERONE ACETATE **Restricted benefit** Hormone-dependent breast cancer; Endometrial cancer.							
2316X	Tablet 200 mg	60	2	..	101.79	35.40	Provera	PF
2725K	Tablet 100 mg	100	2	..	90.38	35.40	Provera	PF
2727M	Tablet 250 mg	60	2	..	125.65	35.40	Provera	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	MEGESTROL ACETATE							
	Restricted benefit							
	Hormone-dependent advanced breast cancer.							
2734X	Tablet 160 mg	30	2	..	83.39	35.40	Megace	QA

Gonadotropin releasing hormone analogues

GOSERELIN ACETATE
Authority required
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate;
Hormone-dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in pre-menopausal women;
Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised);
Hormone-dependent breast cancer as an alternative to adjuvant chemotherapy in peri- or pre-menopausal women.

1454M	Subcutaneous implant 3.6 mg (base) in pre-filled injection syringe	1	5	..	333.00	35.40	Zoladex Implant	AP

GOSERELIN ACETATE
Authority required (STREAMLINED)
3229
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.

8093Y	Subcutaneous implant (long acting) 10.8 mg (base) in pre-filled injection syringe	1	1	..	1108.76	35.40	Zoladex 10.8 Implant	AP

GOSERELIN ACETATE and BICALUTAMIDE
Authority required (STREAMLINED)
3239
Metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

9064C	Pack containing 1 subcutaneous implant goserelin 3.6 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg	‡1	5	..	477.37	35.40	ZolaCos CP 3.6/50	AP
9065D	Pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg	‡1	..	..	1248.29	35.40	ZolaCos CP 10.8/50(28)	AP
9066E	Pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 84 tablets bicalutamide 50 mg	‡1	1	..	1527.37	35.40	ZolaCos CP 10.8/50(84)	AP

LEUPRORELIN ACETATE
Authority required (STREAMLINED)
3229
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.

8707G	Suspension for subcutaneous injection (modified release), 7.5 mg injection set	1	5	..	420.20	35.40	Eligard 1 month	HH
8708H	Suspension for subcutaneous injection (modified release), 22.5 mg injection set	1	1	..	1108.76	35.40	Eligard 3 month	HH
8709J	Suspension for subcutaneous injection (modified release), 30 mg injection set	1	1	..	1451.33	35.40	Eligard 4 month	HH
8859G	Suspension for subcutaneous injection (modified release), 45 mg injection set	1	..	..	2123.98	35.40	Eligard 6 month	HH
8875D	I.M. injection (modified release), powder for injection 7.5 mg with diluent in pre-filled dual-chamber syringe	1	5	..	420.20	35.40	Lucrin Depot 7.5mg PDS	AB
8876E	I.M. injection (modified release), powder for injection 22.5 mg with diluent in pre-filled dual-chamber syringe	1	1	..	1108.76	35.40	Lucrin Depot 3 Month PDS	AB
8877F	I.M. injection (modified release), powder for injection 30 mg with diluent in pre-filled dual-	1	1	..	1451.33	35.40	Lucrin Depot 4 Month PDS	AB

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	chamber syringe								
	TRIPTORELIN								
	Authority required (STREAMLINED)								
	3229								
	Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.								
5297T	Powder for I.M. injection (prolonged release) 22.5 mg (as embonate) with solvent, syringe and needles	1	..	..	2123.98	35.40		Diphereline	IS
9378N	Powder for I.M. injection (prolonged release) 3.75 mg (as embonate) with solvent, syringe and needles	1	5	..	420.20	35.40		Diphereline	IS
9379P	Powder for I.M. injection (prolonged release) 11.25 mg (as embonate) with solvent, syringe and needles	1	1	..	1108.76	35.40		Diphereline	IS

Hormone antagonists and related agents

Anti-estrogens

TAMOXIFEN CITRATE

Restricted benefit

Treatment of hormone-dependent breast cancer.

Note

This drug is not PBS-subsidised for primary prevention of breast cancer.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2109B *NP*	Tablet 10 mg (base)	60	5	..	37.26	35.40		Genox 10	AF
2110C *NP*	Tablet 20 mg (base)	60	5	..	57.55	35.40	[a]	Genox 20	AF
							[a]	GenRx Tamoxifen	GX
							[a]	Tamosin	QA
							[a]	Tamoxen 20 mg	GM
							[a]	Tamoxifen Sandoz	SZ
				[B]3.62	*61.20	35.40	[a]	Nolvadex-D	AP

TOREMIFENE CITRATE

Restricted benefit

Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients.

Note

This drug is not PBS-subsidised for primary prevention of breast cancer.

8216K	Tablet 60 mg (base)	30	5	..	73.74	35.40		Fareston	MK

Anti-androgens

BICALUTAMIDE

Authority required (STREAMLINED)

3674

Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8094B *NP*	Tablet 50 mg	28	5	..	151.64	35.40	[a]	APO-Bicalutamide	TX

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Bicalutamide-GA	GM
							[a]	Bicalutamide Ranbaxy	RA
							[a]	Calutex	QA
							[a]	Cosamide	AF
							[a]	Cosudex	SZ
	CYPROTERONE ACETATE **Authority required (STREAMLINED)** ***1014*** Advanced carcinoma of the prostate; ***1404*** To reduce drive in sexual deviations in males.								
1270W	Tablet 50 mg	100	5	..	*197.98	35.40	[a]	Cyprohexal	SZ
							[a]	Cyprone	AF
							[a]	Cyprostat	SY
							[a]	GenRx Cyproterone Acetate	GX
							[a]	Procur	GM
				[B]3.12	*201.10	35.40	[a]	Androcur	BN
8019C	Tablet 100 mg	50	5	..	161.60	35.40	[a]	Cyprohexal	SZ
							[a]	Cyprostat-100	SY
							[a]	GenRx Cyproterone Acetate	GX
							[a]	Procur 100	GM
				[B]1.56	163.16	35.40	[a]	Androcur-100	BN
	FLUTAMIDE **Authority required (STREAMLINED)** ***3674*** Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1417N *NP*	Tablet 250 mg	100	5	..	201.69	35.40	[a]	Eulexin	MK
							[a]	Flutamin	AF
	NILUTAMIDE **Authority required (STREAMLINED)** ***3675*** Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) analogue therapy; ***3300*** Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8131Y *NP*	Tablet 150 mg	30	5	..	236.56	35.40		Anandron	SW

Antineoplastic and immunomodulating agents

Aromatase inhibitors

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ANASTROZOLE **Restricted benefit** Treatment of hormone-dependent breast cancer in post-menopausal women. **Note** This drug is not PBS-subsidised for primary prevention of breast cancer. This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8179L *NP*	Tablet 1 mg	30	5	..	152.38	35.40	a	Anastrol	QA
							a	Anastrozole-DRLA	RZ
							a	Anastrozole-GA	GM
							a	Anastrozole GH	GQ
							a	Anastrozole-PS	FZ
							a	Anastrozole RBX	RA
							a	Anastrozole Sandoz	SZ
							a	Anastrozole Synthon	ZT
							a	Anzole	WQ
							a	APO-Anastrozole	TX
							a	Arianna	AF
							a	Arimidex	AP
							a	Chem mart Anastrozole	CH
							a	Terry White Chemists Anastrozole	TW
	EXEMESTANE **Restricted benefit** Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate; Treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate. **Note** This drug is not PBS-subsidised for primary prevention of breast cancer. This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8506Q *NP*	Tablet 25 mg	30	5	..	152.38	35.40	a	APO-Exemestane	TX
							a	Aromasin	PF
							a	Exaccord	RA
							a	Exemestane Pfizer	FZ
							a	Exemestane Sandoz	SZ
	LETROZOLE **Restricted benefit** Treatment of hormone-dependent advanced breast cancer in post-menopausal women; Treatment of hormone-dependent early breast cancer in post-menopausal women;								

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Extended adjuvant treatment of hormone-dependent early breast cancer in post-menopausal women commencing within 6 months of ceasing treatment with tamoxifen citrate.								
	Note This drug is not PBS-subsidised for primary prevention of breast cancer. This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years. This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years.								
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8245Y *NP*	Tablet 2.5 mg	30	5	..	152.38	35.40	[a]	APO-Letrozole	TX
							[a]	Chem mart Letrozole	CH
							[a]	Femara 2.5 mg	NV
							[a]	Femolet	AF
							[a]	Fera	QA
							[a]	Letara	FZ
							[a]	Letrozole Actavis	TA
							[a]	Letrozole-DRLA	RZ
							[a]	Letrozole-GA	GM
							[a]	Letrozole generichealth	GQ
							[a]	Letrozole RBX	RA
							[a]	Letrozole Sandoz	SZ
							[a]	Letrozole-Synthon	ZT
							[a]	Terry White Chemists Letrozole	TW

Other hormone antagonists and related agents

DEGARELIX
Authority required (STREAMLINED)
3229
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.

5455D	Powder for injection 80 mg (as acetate), injection set	1	5	..	420.20	35.40		Firmagon 80mg	FP

DEGARELIX
Authority required (STREAMLINED)
3229
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.

Note
No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

5456E	Powder for injection 120 mg (as acetate), 2, injection set	‡1	..	..	438.72	35.40		Firmagon 120mg	FP

Immunostimulants

Immunostimulants

Interferons

INTERFERON ALFA-2a
Caution
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Authority required Hairy cell leukaemia; Myeloproliferative disease with excessive thrombocytosis.							
8180M	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	15	4	..	*506.22	35.40	Roferon-A	RO
	INTERFERON ALFA-2a **Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. **Authority required** Myeloproliferative disease with excessive thrombocytosis.							
8551C	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*264.72	35.40	Roferon-A	RO
8552D	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*344.72	35.40	Roferon-A	RO
8553E	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*506.12	35.40	Roferon-A	RO
	INTERFERON ALFA-2a **Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. **Authority required** Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy.							
8181N	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	15	5	..	*506.22	35.40	Roferon-A	RO
8182P	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*264.72	35.40	Roferon-A	RO
8183Q	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*344.72	35.40	Roferon-A	RO
8184R	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*506.12	35.40	Roferon-A	RO
	INTERFERON ALFA-2b **Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. **Authority required** Hairy cell leukaemia.							
8572E	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	3	4	..	*606.03	35.40	Intron A Redipen	MK
	INTERFERON ALFA-2b **Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. **Authority required** Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy; Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy.							
8348J	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	3	5	..	*606.03	35.40	Intron A Redipen	MK
8476D	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	3	5	..	*1005.75	35.40	Intron A Redipen	MK

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	INTERFERON BETA-1a							
	Authority required							
	Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule;							
	Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.							
8289G	Injection set comprising 1 vial powder for injection 30 micrograms (6,000,000 i.u.) with diluent	4	5	..	1056.77	35.40	Avonex	BD
8403G	Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose pre-filled syringe	12	5	..	1056.77	35.40	Rebif 44	SG
8805K	Injection 30 micrograms (6,000,000 i.u.) in 0.5 mL single dose pre-filled syringe	4	5	..	1056.77	35.40	Avonex	BD
8968B	Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector	12	5	..	1056.77	35.40	Rebif 44	SG
9332E	Solution for injection 132 micrograms in 1.5 mL multidose cartridge	4	5	..	1056.77	35.40	Rebif 44	SG
	INTERFERON BETA-1b							
	Authority required							
	Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule;							
	Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.							
8101J	Injection set including 1 vial powder for injection 8,000,000 i.u. (250 micrograms) and solvent	15	5	..	1180.16	35.40	Betaferon	BN

Other immunostimulants

	BCG IMMUNOTHERAPEUTIC (Bacillus Calmette-Guérin/ Connaught strain)							
	Restricted benefit							
	Treatment of carcinoma in situ of the urinary bladder.							
1140B	Powder for intravesical administration containing 6.6 to 19.2 x 10^8 CFU	3	1	..	*459.87	35.40	ImmuCyst	SW
	BCG-TICE (Bacillus Calmette-Guérin/ Tice strain)							
	Restricted benefit							
	Primary and relapsing superficial urothelial carcinoma of the bladder.							
1131M	Vial containing powder for intravesical administration approximately 5 x 10^8 CFU	3	1	..	556.39	35.40	OncoTICE	MK
	GLATIRAMER ACETATE							
	Authority required							
	Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule;							
	Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.							

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
8726G	Injection 20 mg in 1 mL single dose pre-filled syringe	28	5	..	1092.65	35.40	Copaxone	CS

Immunosuppressants

Immunosuppressants

Selective immunosuppressants

ABATACEPT

Note

Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or

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intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Note
Special Pricing Arrangements apply.

1220F	Injection 125 mg in 1 mL single dose pre-filled syringe	4	3	..	1753.91	35.40	Orencia	BQ

ABATACEPT

Note
Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Authority required Continuing treatment Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults: (a) who have a documented history of severe active rheumatoid arthritis; and (b) who have demonstrated an adequate response to treatment with abatacept; and (c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or — shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of 24 weeks of treatment will be approved under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** Special Pricing Arrangements apply.							
1221G	Injection 125 mg in 1 mL single dose pre-filled syringe	4	5	..	1753.91	35.40	Orencia	BQ
	EVEROLIMUS **Caution** Careful monitoring of patients is mandatory. **Authority required** Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with: (a) renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; (b) cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.							
8840G	Tablet 0.25 mg	60	3	..	282.79	35.40	Certican	NV
8841H	Tablet 0.5 mg	60	3	..	543.83	35.40	Certican	NV
8842J	Tablet 0.75 mg	120	3	..	*1578.62	35.40	Certican	NV
9352F	Tablet 1 mg	120	3	..	*2068.76	35.40	Certican	NV
	FINGOLIMOD **Authority required** Initial treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI							

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule; Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug and who has demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule. **Note** Special Pricing Arrangements apply.								
5262Y	Capsule 500 micrograms (as hydrochloride)	28	5	..	2312.98	35.40		Gilenya	NV
	LEFLUNOMIDE **Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out. **Authority required (STREAMLINED)** ***2643*** Initial treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician; ***2681*** Initial treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician. **Note** No applications for increased maximum quantities and/or repeats will be authorised.								
8373Q	Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg	‡1	..	..	175.64	35.40		Arava	SW
	LEFLUNOMIDE **Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out. **Authority required (STREAMLINED)** ***2644*** Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.								
8374R	Tablet 10 mg	30	5	..	76.80	35.40	[a]	APO-Leflunomide	TX
							[a]	Arabloc	AV
							[a]	Arava	SW
							[a]	Lunava 10	ZP
8375T	Tablet 20 mg	30	5	..	113.57	35.40	[a]	APO-Leflunomide	TX
							[a]	Arabloc	AV
							[a]	Arava	SW
							[a]	Lunava 20	ZP
	LEFLUNOMIDE **Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out. **Authority required (STREAMLINED)** ***2682*** Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.								
5449T	Tablet 10 mg	30	5	..	76.80	35.40	[a]	Arabloc	AV
							[a]	Arava	SW
5450W	Tablet 20 mg	30	5	..	113.57	35.40	[a]	Arabloc	AV

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							[a]	Arava	SW
	MYCOPHENOLATE MOFETIL **Caution** Careful monitoring of patients is mandatory. **Authority required** Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with: (a) renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; (b) cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.								
8649F	Capsule 250 mg	300	3	..	*528.36	35.40	[a]	APO-Mycophenolate	TX
							[a]	CellCept	RO
							[a]	Imulate	QA
							[a]	Mycophenolate Sandoz	SZ
							[a]	Pharmacor Mycophenolate 250	CR
				..	*528.42	35.40	[a]	Ceptolate	AF
8650G	Tablet 500 mg	150	3	..	*528.36	35.40	[a]	APO-Mycophenolate	TX
							[a]	CellCept	RO
							[a]	Ceptolate	AF
							[a]	Imulate	QA
							[a]	Mycophenolate Sandoz	SZ
							[a]	Pharmacor Mycophenolate 500	CR
8651H	Powder for oral suspension 1 g per 5 mL, 165 mL	‡1	3	..	#289.90	35.40		CellCept	RO
	MYCOPHENOLATE SODIUM **Caution** Careful monitoring of patients is mandatory. **Authority required** Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate sodium and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.								
8652J	Tablet (enteric coated) 180 mg (mycophenolic acid)	120	3	..	225.18	35.40		Myfortic	NV
8653K	Tablet (enteric coated) 360 mg (mycophenolic acid)	120	3	..	425.93	35.40		Myfortic	NV
	SIROLIMUS **Caution** Careful monitoring of patients is mandatory. **Authority required** Maintenance therapy, following initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.								
8724E	Tablet 1 mg	100	3	..	815.25	35.40		Rapamune	PF
8725F	Oral solution 1 mg per mL, 60 mL	‡1	3	..	529.74	35.40		Rapamune	PF
8833X	Tablet 2 mg	100	3	..	1583.69	35.40		Rapamune	PF
8984W	Tablet 0.5 mg	100	3	..	413.29	35.40		Rapamune	PF

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Tumor necrosis factor alpha (TNF-alpha) inhibitors

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2

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infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated

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a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

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If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

No applications for increased maximum quantities and/or repeats will be authorised.
Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with adalimumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved. **Note** Special Pricing Arrangements apply.							
8737W	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1774.36	35.40	Humira	AB
9099X	Injection 40 mg in 0.8 mL pre-filled pen	2	3	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Continuing treatment

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with adalimumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with adalimumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of 24 weeks of treatment will be approved under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved. **Note** Special Pricing Arrangements apply.							
8741C	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	35.40	Humira	AB
9100Y	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority

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prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial adalimimab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial 2

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with adalimumab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with adalimumab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased maximum quantities and/or repeats will be authorised.
Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

9033K	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1774.36	35.40	Humira	AB
9101B	Injection 40 mg in 0.8 mL pre-filled pen	2	3	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

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Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with adalimumab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab.

An adequate response to treatment with adalimumab is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.							
	Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.							
	Note No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.							
9034L	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	35.40	Humira	AB
9102C	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1

Antineoplastic and immunomodulating agents

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NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

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Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required

Initial 2 (change or re-commencement for all patients)
Initial PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with adalimumab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Note

No applications for increased maximum quantities and/or repeats will be authorised.
Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

9077R	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1774.36	35.40	Humira	AB
9103D	Injection 40 mg in 0.8 mL pre-filled pen	2	3	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa

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antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated an adequate response to treatment with adalimumab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with adalimumab.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment

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	must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with adalimumab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle. **Note** No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.							
9078T	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	35.40	Humira	AB
9104E	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:

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(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a

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corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would

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otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and

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(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment of adalimumab will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9186L	Injection 40 mg in 0.8 mL pre-filled syringe, 6	1	..	..	5036.36	35.40	Humira	AB
9187M	Injection 40 mg in 0.8 mL pre-filled pen, 6	1	..	..	5036.36	35.40	Humira	AB
9188N	Injection 40 mg in 0.8 mL pre-filled syringe	2	2	..	1774.36	35.40	Humira	AB
9190Q	Injection 40 mg in 0.8 mL pre-filled pen	2	2	..	1774.36	35.40	Humira	AB

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 3 (grandfather)
Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with adalimumab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.
Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or
(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks of treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

intestine; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 3
Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive

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protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with adalimumab for Crohn disease as specified in the criteria for continuing treatment with adalimumab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of this application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

9189P	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	35.40	Humira	AB
9191R	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note
Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required
Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment. A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction. Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks. A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss. It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** Special Pricing Arrangements apply.								
9425C	Injection 40 mg in 0.8 mL pre-filled syringe	2	4	..	1774.36	35.40	Humira	AB
9426D	Injection 40 mg in 0.8 mL pre-filled pen	2	4	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with adalimumab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with adalimumab.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and
(c) who have demonstrated an adequate response to treatment with adalimumab.

An adequate response to adalimumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Special Pricing Arrangements apply.							
9427E	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	35.40	Humira	AB
9428F	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Authority required

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:
(a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND
(b) has received no PBS-subsidised treatment with a bDMARD for this condition in the previous 12 months; and
(c) has failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg per day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Authority required

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with adalimumab by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:
(a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

5281Y	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1774.36	35.40	Humira	AB
5282B	Injection 40 mg in 0.8 mL pre-filled pen	2	3	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

Authority required

Initial 3 ('grandfather' patients).

Initial PBS-subsidised supply for continuing treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:
(a) has a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; and
(b) was receiving treatment with adalimumab prior to 1 March 2010; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and
(d) is receiving treatment with adalimumab at the time of application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

A maximum of 24 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled in order to ensure continuity of treatment for those patients who meet the continuation criterion.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Authority required
Continuing treatment.

Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older:
(a) who has a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; and
(b) who has demonstrated an adequate response to treatment with adalimumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with adalimumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) an active joint count of fewer than 10 active (swollen and tender) joints; or
(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(iii) a reduction in the number of the following active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

5283C	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	35.40	Humira	AB
5284D	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	35.40	Humira	AB

ADALIMUMAB
Note
Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has an externally draining enterocutaneous or rectovaginal fistula; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(a) two completed authority prescription forms; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required

Initial 2
Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
8961P	Injection 40 mg in 0.8 mL pre-filled syringe, 6	1	..	..	5036.36	35.40	Humira	AB
8962Q	Injection 40 mg in 0.8 mL pre-filled pen, 6	1	..	..	5036.36	35.40	Humira	AB
8963R	Injection 40 mg in 0.8 mL pre-filled syringe	2	2	..	1774.36	35.40	Humira	AB
8965W	Injection 40 mg in 0.8 mL pre-filled pen	2	2	..	1774.36	35.40	Humira	AB

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 3 (grandfather)
Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:
(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and
(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) is receiving treatment with adalimumab at the time of application; and
(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
No applications for increased maximum quantities and/or repeats will be authorised.

8964T	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	35.40	Humira	AB
8966X	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	35.40	Humira	AB

CERTOLIZUMAB PEGOL

Note
Any queries concerning the arrangements to prescribe certolizumab pegol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe certolizumab pegol should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 18 to 20 weeks of treatment depending on the dosage regimen will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 18 or 20 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with certolizumab pegol.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required
Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with certolizumab pegol and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised certolizumab pegol treatment, within the timeframes specified below.

A maximum of 18 to 20 weeks of treatment depending on the dosage regimen will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 18 or 20 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required
Continuing treatment

Continuing PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with certolizumab pegol; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with certolizumab pegol.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of 24 weeks of treatment will be approved under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with certolizumab pegol must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with certolizumab pegol, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** Special Pricing Arrangements apply.							
3425G	Injection 200 mg in 1 mL single use pre-filled syringe	2	5	..	1708.64	35.40	Cimzia	UC

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.							
	Authority required Initial 2 (change or re-commencement after break of less than 24 months) Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have a documented history of severe active rheumatoid arthritis; and (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. Applications for patients who have received PBS-subsidised treatment with etanercept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below. A maximum of 16 weeks of treatment will be authorised under this restriction. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** Special Pricing Arrangements apply.							
8637N	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1829.00	35.40	Enbrel	PF
9089J	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1774.37	35.40	Enbrel	PF
9459W	Injection 50 mg in 1 mL single use auto-injector, 4	1	3	..	1774.37	35.40	Enbrel	PF

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two

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prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with etanercept; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with etanercept.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Note
Special Pricing Arrangements apply.

8638P	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1829.00	35.40	Enbrel	PF
9090K	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1774.37	35.40	Enbrel	PF
9460X	Injection 50 mg in 1 mL single use auto-injector, 4	1	5	..	1774.37	35.40	Enbrel	PF

ETANERCEPT
Note
Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial 2
Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with etanercept during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with etanercept within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
9035M	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1829.00	35.40	Enbrel	PF
9087G	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1774.37	35.40	Enbrel	PF
9457R	Injection 50 mg in 1 mL single use auto-injector, 4	1	3	..	1774.37	35.40	Enbrel	PF

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with etanercept; and

(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept.

An adequate response to treatment with etanercept is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9036N	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1829.00	35.40	Enbrel	PF
9088H	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1774.37	35.40	Enbrel	PF
9458T	Injection 50 mg in 1 mL single use auto-injector, 4	1	5	..	1774.37	35.40	Enbrel	PF

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

GPO Box 9826
HOBART TAS 7001

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Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required

Initial 2 (change or re-commencement for all patients)
Initial PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with etanercept in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone. Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
8778B	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1829.00	35.40	Enbrel	PF
9085E	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1774.37	35.40	Enbrel	PF
9455P	Injection 50 mg in 1 mL single use auto-injector, 4	1	3	..	1774.37	35.40	Enbrel	PF

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured. (5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab. A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details. **Authority required** Continuing treatment for all patients Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who: (a) has demonstrated an adequate response to treatment with etanercept; and (b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au]. All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with etanercept will be authorised under this criterion. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone. All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with etanercept. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
8779C	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1829.00	35.40	Enbrel	PF
9086F	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1774.37	35.40	Enbrel	PF
9456Q	Injection 50 mg in 1 mL single use auto-injector, 4	1	5	..	1774.37	35.40	Enbrel	PF

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

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All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Special Pricing Arrangements apply.

9037P	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1829.00	35.40	Enbrel	PF
9091L	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1774.37	35.40	Enbrel	PF

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
9461Y	Injection 50 mg in 1 mL single use auto-injector, 4	1	3	..	1774.37	35.40	Enbrel	PF

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on

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treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with etanercept.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to treatment with etanercept.

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].							
	The most recent PASI assessment must be no more than 1 month old at the time of application.							
	A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.							
	Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.							
	A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.							
	It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.							
	The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.							
	Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
	Note Special Pricing Arrangements apply.							
9429G	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1829.00	35.40	Enbrel	PF
9431J	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1774.37	35.40	Enbrel	PF
9462B	Injection 50 mg in 1 mL single use auto-injector, 4	1	5	..	1774.37	35.40	Enbrel	PF
	ETANERCEPT							
	Note Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.							
	Written applications for authority to prescribe etanercept should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
	;							
	Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS							
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.							
	A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.							
	From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a							

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patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:
(a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND
(b) has received no PBS-subsidised treatment with a bDMARD for this condition in the previous 12 months; and
(c) has failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg per day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium

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aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Authority required

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with etanercept by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:
(a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and
(c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	within the timeframes specified below.							
	A maximum of 16 weeks of treatment will be authorised under this restriction.							
	Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with etanercept may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.							
	Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.							
	Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.							
	If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.							
3445H	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1829.00	35.40	Enbrel	PF
3446J	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1774.37	35.40	Enbrel	PF
3447K	Injection 50 mg in 1 mL single use auto-injector, 4	1	3	..	1774.37	35.40	Enbrel	PF

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

Authority required

Continuing treatment.

Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older:
(a) who has a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; and
(b) who has demonstrated an adequate response to treatment with etanercept; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with etanercept.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) an active joint count of fewer than 10 active (swollen and tender) joints; or
(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(iii) a reduction in the number of the following active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

3448L	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1829.00	35.40	Enbrel	PF
3449M	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1774.37	35.40	Enbrel	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
3450N	Injection 50 mg in 1 mL single use auto-injector, 4	1	5	..	1774.37	35.40	Enbrel	PF

GOLIMUMAB

Note

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required
Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with golimumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Where the most recent course of PBS-subsidised golimumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised golimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** Special Pricing Arrangements apply.							
3426H	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	3	..	1777.29	35.40	Simponi	JC
3427J	Injection 50 mg in 0.5 mL single use pre-filled pen	1	3	..	1777.29	35.40	Simponi	JC

GOLIMUMAB

Note

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Continuing treatment

Continuing PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with golimumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with golimumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	A maximum of 24 weeks of treatment will be approved under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** Special Pricing Arrangements apply.							
3428K	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	5	..	1777.29	35.40	Simponi	JC
3429L	Injection 50 mg in 0.5 mL single use pre-filled pen	1	5	..	1777.29	35.40	Simponi	JC

GOLIMUMAB

Note

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1

Initial PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial 2

Initial PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with golimumab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with golimumab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised golimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised golimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note
No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved.

3430M	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	3	..	1777.29	35.40	Simponi	JC
3431N	Injection 50 mg in 0.5 mL single use pre-filled pen	1	3	..	1777.29	35.40	Simponi	JC

GOLIMUMAB

Note
Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle,

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 3 — grandfather golimumab patients
Initial PBS-subsidised supply for continuing treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) were receiving treatment with golimumab prior to 1 March 2010; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with golimumab; and
(4) are receiving treatment with golimumab at the time of application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 24 weeks of treatment with golimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with golimumab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with golimumab.

An adequate response to treatment with golimumab is defined as:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note
No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved.

3432P	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	5	..	1777.29	35.40	Simponi	JC
3433Q	Injection 50 mg in 0.5 mL single use pre-filled pen	1	5	..	1777.29	35.40	Simponi	JC

GOLIMUMAB

Note
Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with golimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with golimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required

Initial 2 (change or re-commencement for all patients)
Initial PBS-subsidised treatment with golimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with golimumab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised golimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

A maximum of 16 weeks of treatment with golimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Note

No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved.

3434R	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	3	..	1777.29	35.40	Simponi	JC
3435T	Injection 50 mg in 0.5 mL single use pre-filled pen	1	3	..	1777.29	35.40	Simponi	JC

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

GOLIMUMAB

Note

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Authority required

Initial ('grandfather' patients)

Initial PBS-subsidised supply for continuing treatment with golimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who was receiving treatment with golimumab prior to 1 March 2010; and
(a) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with golimumab; and
(b) is receiving treatment with golimumab at the time of application.

The BASDAI assessment and ESR and/or CRP measurements provided must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a signed patient acknowledgment form.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of the course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Patients may only qualify for PBS-subsidised treatment under this criterion once.

Authority required

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated an adequate response to treatment with golimumab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with golimumab.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with golimumab. If

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle. **Note** No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved.							
3436W	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	5	..	1777.29	35.40	Simponi	JC
3437X	Injection 50 mg in 0.5 mL single use pre-filled pen	1	5	..	1777.29	35.40	Simponi	JC

Interleukin inhibitors

USTEKINUMAB

Note

Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Note

No applications for increased repeats will be authorised.

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased repeats will be authorised.

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Note

No applications for increased repeats will be authorised.

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note
No applications for increased repeats will be authorised.

Note
Special Pricing Arrangements apply.

9304Q	Injection 45 mg in 0.5 mL	1	2	..	4601.42	35.40	Stelara	JC

USTEKINUMAB

Note
Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with ustekinumab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with ustekinumab.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased repeats will be authorised.

Authority required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and
(c) who have demonstrated an adequate response to treatment with ustekinumab.

An adequate response to ustekinumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased repeats will be authorised.

Note

Special Pricing Arrangements apply.

9305R	Injection 45 mg in 0.5 mL	1	1	..	4601.42	35.40	Stelara	JC

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Calcineurin inhibitors								
	CYCLOSPORIN								
	Caution								
	Careful monitoring of patients is mandatory.								
	Authority required								
	Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of: (a) patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application;								
	(b) patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate. Therapy must remain under the supervision and direction of a dermatologist, clinical immunologist or specialised unit reviewing the patient. The name of the dermatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application;								
	(c) patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life. Therapy must remain under the supervision and direction of a dermatologist or specialised unit reviewing the patient. The name of the dermatologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application;								
	(d) patients with nephrotic syndrome in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired. Therapy must remain under the supervision and direction of a nephrologist or specialised unit reviewing the patient. The name of the nephrologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application;								
	(e) patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate. Therapy must remain under the supervision and direction of a rheumatologist, clinical immunologist or specialised unit reviewing the patient. The name of the rheumatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application;								
	Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate;								
	Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life;								
	Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate.								
8657P	Capsule 10 mg	120	3	..	*94.42	35.40		Neoral 10	NV
8658Q	Capsule 25 mg	60	3	..	*97.24	35.40	a	Cicloral	SZ
							a	Neoral 25	NV
8659R	Capsule 50 mg	60	3	..	*195.38	35.40	a	Cicloral	SZ
				B2.50	*197.88	35.40	a	Neoral 50	NV
8660T	Capsule 100 mg	60	3	..	*374.44	35.40	a	Cicloral	SZ
				B3.00	*377.44	35.40	a	Neoral 100	NV
8661W	Oral liquid 100 mg per mL, 50 mL	2	3	..	*712.66	35.40		Neoral	NV
	TACROLIMUS								
	Caution								
	Careful monitoring of patients is mandatory.								
	Authority required								
	Maintenance therapy, following initiation and stabilisation of treatment with tacrolimus, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.								
5299X	Capsule 0.5 mg (once daily prolonged release)	30	3	..	64.59	35.40		Prograf XL	JC
5300Y	Capsule 1 mg (once daily prolonged release)	60	3	..	235.91	35.40		Prograf XL	JC
5451X	Capsule 5 mg (once daily prolonged release)	30	3	..	556.32	35.40		Prograf XL	JC
8646C	Capsule 0.5 mg	100	3	..	200.30	35.40	a	Prograf	JC
							a	Tacrolimus Sandoz	SZ
8647D	Capsule 1 mg	100	3	..	376.91	35.40	a	Prograf	JC
							a	Tacrolimus Sandoz	SZ
8648E	Capsule 5 mg	50	3	..	922.44	35.40	a	Prograf	JC
							a	Tacrolimus Sandoz	SZ

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Other immunosuppressants								
	AZATHIOPRINE								
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2687K *NP*	Tablet 50 mg	100	5	..	48.06	35.40	[a]	Azamun	GM
							[a]	Azapin	QA
							[a]	Azathioprine Sandoz	SZ
							[a]	GenRx Azathioprine	GX
							[a]	Imuran	AS
							[a]	Thioprine	AF
2688L *NP*	Tablet 25 mg	100	5	..	31.51	32.60	[a]	Azathioprine Sandoz	SZ
							[a]	Imuran	AS
	METHOTREXATE								
1622J	Tablet 2.5 mg	30	5	..	13.12	14.21	[a]	Hospira Pty Limited	HH
							[a]	Methoblastin	PF
2272N	Tablet 10 mg	15	3	..	21.84	22.93		Methoblastin	PF
	METHOTREXATE								
	Restricted benefit								
	For patients requiring doses greater than 20 mg per week.								
1623K	Tablet 10 mg	50	2	..	45.28	35.40		Methoblastin	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Musculo-skeletal system

Antiinflammatory and antirheumatic products

Antiinflammatory and antirheumatic products, non-steroids

Acetic acid derivatives and related substances

DICLOFENAC SODIUM

1302M *NP,MW*	Suppository 100 mg	40	3	..	*24.92	26.01		Voltaren 100	NV

DICLOFENAC SODIUM
Restricted benefit
Chronic arthropathies (including osteoarthritis) with an inflammatory component;
Bone pain due to malignant disease.

1299J *NP*	Tablet 25 mg (enteric coated)	100	3	..	*12.74	13.83	a	APO-Diclofenac	TX
							a	Chem mart Diclofenac	CH
							a	Clonac 25	QA
							a	Diclofenac-GA	GM
							a	Diclofenac Sandoz	SZ
							a	Fenac 25	AF
							a	Terry White Chemists Diclofenac	TW
				B2.32	*15.06	13.83	a	Voltaren 25	NV
1300K *NP*	Tablet 50 mg (enteric coated)	50	3	..	10.82	11.91	a	APO-Diclofenac	TX
							a	Chem mart Diclofenac	CH
							a	Clonac 50	QA
							a	Diclofenac-GA	GM
							a	Diclofenac Sandoz	SZ
							a	Fenac	AF
							a	Terry White Chemists Diclofenac	TW
				B2.34	13.16	11.91	a	Voltaren 50	NV

INDOMETHACIN

2757D *NP*	Suppository 100 mg	40	3	..	*22.50	23.59		Indocid	AS

INDOMETHACIN
Restricted benefit
Chronic arthropathies (including osteoarthritis) with an inflammatory component;
Bone pain due to malignant disease.

2454E *NP*	Capsule 25 mg	100	3	..	*12.42	13.51	a	Arthrexin	AF
				B2.02	*14.44	13.51	a	Indocid	AS

Oxicams

MELOXICAM

Note

The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Symptomatic treatment of osteoarthritis;

Symptomatic treatment of rheumatoid arthritis.

Note

Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8561N *NP*	Tablet 7.5 mg	30	3	..	17.46	18.55	a	Chem mart Meloxicam 7.5 mg	CH
							a	GenRx Meloxicam	GX
							a	Meloxibell	BF
							a	Meloxicam-GA	GM
							a	Meloxicam Ranbaxy	RA
							a	Meloxicam Sandoz	SZ
							a	Movalis 7.5	QA
							a	Moxicam 7.5	AF
							a	Pharmacor Meloxicam 7.5	CR
							a	Terry White Chemists Meloxicam 7.5 mg	TW
				B 1.76	19.22	18.55	a	Mobic	BY
8887R *NP*	Capsule 7.5 mg	30	3	..	17.46	18.55	a	APO-Meloxicam	TX
							a	Chem mart Meloxicam	CH
							a	Mobic	BY
							a	Movalis 7.5	QA
							a	Terry White Chemists Meloxicam	TW

MELOXICAM

Note

The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Symptomatic treatment of osteoarthritis;

Symptomatic treatment of rheumatoid arthritis.

Note

Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

8562P *NP*	Tablet 15 mg	30	3	..	22.53	23.62	a	Chem mart Meloxicam 15 mg	CH
							a	GenRx Meloxicam	GX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Meloxibell	BF
							[a]	Meloxicam-GA	GM
							[a]	Meloxicam Ranbaxy	RA
							[a]	Meloxicam Sandoz	SZ
							[a]	Movalis 15	QA
							[a]	Moxicam 15	AF
							[a]	Pharmacor Meloxicam 15	CR
							[a]	Terry White Chemists Meloxicam 15 mg	TW
				[B]1.76	24.29	23.62	[a]	Mobic	BY
8888T *NP*	Capsule 15 mg	30	3	..	22.53	23.62	[a]	APO-Meloxicam	TX
							[a]	Chem mart Meloxicam	CH
							[a]	Mobic	BY
							[a]	Movalis 15	QA
							[a]	Terry White Chemists Meloxicam	TW
	PIROXICAM **Restricted benefit** Chronic arthropathies (including osteoarthritis) with an inflammatory component.								
1895R *NP*	Dispersible tablet 10 mg	50	3	..	12.20	13.29		Mobilis D-10	AF
1896T *NP*	Dispersible tablet 20 mg	25	3	..	11.92	13.01	[a]	Mobilis D-20	AF
				[B]2.49	14.41	13.01	[a]	Feldene-D	PF
1897W *NP*	Capsule 10 mg	50	3	..	12.20	13.29	[a]	Chem mart Piroxicam	CH
							[a]	GenRx Piroxicam	GX
							[a]	Mobilis 10	AF
							[a]	Terry White Chemists Piroxicam	TW
				[B]2.52	14.72	13.29	[a]	Feldene	PF
1898X *NP*	Capsule 20 mg	25	3	..	11.92	13.01	[a]	Chem mart Piroxicam	CH
							[a]	GenRx Piroxicam	GX
							[a]	Mobilis 20	AF
							[a]	Terry White Chemists Piroxicam	TW
				[B]2.49	14.41	13.01	[a]	Feldene	PF

Propionic acid derivatives

IBUPROFEN

3192B *NP,MW*	Tablet 400 mg	30	..	..	9.19	10.28		Brufen	AB

IBUPROFEN
Restricted benefit
Chronic arthropathies (including osteoarthritis) with an inflammatory component;

Bone pain due to malignant disease.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
3190X *NP*	Tablet 400 mg	90	3	..	*14.73	15.82		Brufen	AB
	KETOPROFEN								
1588N *NP*	Suppository 100 mg	40	3	..	*25.30	26.39		Orudis	SW
	KETOPROFEN **Restricted benefit** Chronic arthropathies (including osteoarthritis) with an inflammatory component.								
1590Q *NP*	Capsule 200 mg (sustained release)	28	3	..	19.10	20.19	a	Oruvail SR	AV
				[B]2.21	21.31	20.19	a	Orudis SR 200	SW
	NAPROXEN **Restricted benefit** Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.								
1614Y *NP*	Tablet 750 mg (sustained release)	28	3	..	12.08	13.17	a	Proxen SR 750	MD
				[B]1.22	13.30	13.17	a	Naprosyn SR750	RO
1615B *NP*	Tablet 1 g (sustained release)	28	3	..	13.96	15.05	a	Proxen SR 1000	MD
				[B]1.29	15.25	15.05	a	Naprosyn SR1000	RO
1659H *NP*	Tablet 500 mg	50	3	..	12.58	13.67	a	Inza 500	AF
				[B]1.30	13.88	13.67	a	Naprosyn	RO
1674D *NP*	Tablet 250 mg	100	3	..	*13.34	14.43	a	Inza 250	AF
				[B]2.24	*15.58	14.43	a	Naprosyn	RO
	NAPROXEN SODIUM **Restricted benefit** Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease. **Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.								
1795L *NP*	Tablet 550 mg	50	3	..	12.77	13.86	a	Crysanal	MD
				[B]2.17	14.94	13.86	a	Anaprox 550	RO
	TIAPROFENIC ACID **Caution** Cystitis and other urinary disorders have been reported with this drug. **Note** The recommended maximum dose is 600 mg per day. **Restricted benefit** Chronic arthropathies (including osteoarthritis) with an inflammatory component.								
2103Q *NP*	Tablet 300 mg	60	3	..	17.58	18.67		Surgam	SW

Fenamates

MEFENAMIC ACID
Restricted benefit
Dysmenorrhoea;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Menorrhagia.							
1824B *NP*	Capsule 250 mg	50	2	..	18.16	19.25	Ponstan	PF

Coxibs

CELECOXIB

Note

The use of celecoxib for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Symptomatic treatment of osteoarthritis;

Symptomatic treatment of rheumatoid arthritis.

8439E *NP*	Capsule 100 mg	60	3	..	32.31	33.40	Celebrex	PF
8440F *NP*	Capsule 200 mg	30	3	..	32.31	33.40	Celebrex	PF

Specific antirheumatic agents

Quinolines

HYDROXYCHLOROQUINE SULFATE

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1512N *NP*	Tablet 200 mg	100	1	..	37.59	35.40	Plaquenil	SW

Gold preparations

AURANOFIN

Caution

Regular blood and urine checks are essential.

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1095P *NP*	Tablet 3 mg	60	5	..	63.55	35.40	Ridaura	GH

SODIUM AUROTHIOMALATE

Caution

Regular blood and urine checks are essential.

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2016D *NP*	Injection 10 mg	10	..	..	67.03	35.40	Myocrisin	SW
2017E *NP*	Injection 20 mg	10	1	..	102.67	35.40	Myocrisin	SW
2018F *NP*	Injection 50 mg	10	1	..	152.47	35.40	Myocrisin	SW

Penicillamine and similar agents

PENICILLAMINE

Caution

Regular blood and urine checks are essential.

Musculo-skeletal system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2721F *NP*	Tablet 125 mg	100	1	..	31.63	32.72		D-Penamine	AL
2838J *NP*	Tablet 250 mg	100	1	..	53.29	35.40		D-Penamine	AL

Muscle relaxants

Muscle relaxants, centrally acting agents

Other centrally acting agents

BACLOFEN

2729P *NP*	Tablet 10 mg	100	5	..	23.22	24.31	a	Chem mart Baclofen	CH
							a	Clofen 10	AF
							a	GenRx Baclofen	GX
							a	Stelax 10	QA
							a	Terry White Chemists Baclofen	TW
				B1.50	24.72	24.31	a	Lioresal 10	NV
2730Q *NP*	Tablet 25 mg	100	5	..	42.87	35.40	a	Chem mart Baclofen	CH
							a	Clofen 25	AF
							a	GenRx Baclofen	GX
							a	Stelax 25	QA
							a	Terry White Chemists Baclofen	TW
				B1.29	44.16	35.40	a	Lioresal 25	NV

Muscle relaxants, directly acting agents

Dantrolene and derivatives

DANTROLENE SODIUM

Restricted benefit

Treatment of chronic spasticity.

1779P *NP*	Capsule 25 mg	100	2	..	72.04	35.40		Dantrium	PF
1780Q *NP*	Capsule 50 mg	100	2	..	81.81	35.40		Dantrium	PF

Antigout preparations

Antigout preparations

Preparations inhibiting uric acid production

ALLOPURINOL

Note

The dose should be adjusted in accordance with renal function.

2600W *NP*	Tablet 100 mg	200	2	..	12.86	13.95	a	Allopurinol Sandoz	SZ
							a	Allosig	FM
							a	Chem mart Allopurinol	CH
							a	GenRx Allopurinol	GX
							a	Terry White Chemists	TW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Allopurinol	
				[B]2.85	15.71	13.95	[a]	Zyloprim	QA
				..	*12.86	13.95	[a]	Progout 100	AF
2604C *NP*	Tablet 300 mg	60	2	..	10.23	11.32	[a]	Allopurinol Sandoz	SZ
							[a]	Allosig	FM
							[a]	Chem mart	CH
								Allopurinol	
							[a]	GenRx Allopurinol	GX
							[a]	Progout 300	AF
							[a]	Terry White Chemists	TW
								Allopurinol	
				[B]2.85	13.08	11.32	[a]	Zyloprim	QA

Preparations increasing uric acid excretion

PROBENECID

1940D *NP*	Tablet 500 mg	100	5	..	75.69	35.40		Pro-Cid	PL

Preparations with no effect on uric acid metabolism

COLCHICINE

3410L *NP*	Tablet 500 micrograms	30	5	..	11.00	12.09	[a]	Lengout	LN
				[B]0.85	11.85	12.09	[a]	Colgout	AS

Drugs for treatment of bone diseases

Drugs affecting bone structure and mineralization

Bisphosphonates

ALENDRONATE SODIUM

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

3933

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8511Y *NP*	Tablet equivalent to 70 mg alendronic acid	4	5	..	27.52	28.61	[a]	Adronat	AF
							[a]	Alendrobell 70mg	BF
							[a]	Alendronate-GA	GM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Alendronate Sandoz	SZ
							[a]	Alendro Once Weekly	QA
							[a]	APO-Alendronate	TX
							[a]	Chem mart Alendronate 70mg	CH
							[a]	Densate 70	DO
							[a]	Ossmax 70mg	RA
							[a]	Terry White Chemists Alendronate 70mg	TW
				[B]2.05	29.57	28.61	[a]	Fosamax Once Weekly	MK

ALENDRONATE SODIUM

Authority required (STREAMLINED)

3256

Symptomatic Paget disease of bone.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8090T *NP*	Tablet equivalent to 40 mg alendronic acid	30	5	..	73.07	35.40		Fosamax 40 mg	MK

DISODIUM ETIDRONATE

Authority required (STREAMLINED)

3257

Symptomatic Paget disease of bone when calcitonin has been found to be unsatisfactory due to lack of efficacy;

3258

Symptomatic Paget disease of bone when calcitonin has been found to be unsatisfactory due to unacceptable side effects;

1153

Heterotopic ossification.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2920Q *NP*	Tablet 200 mg	60	5	..	115.17	35.40		Didronel	PF

DISODIUM PAMIDRONATE

Authority required (STREAMLINED)

3256

Symptomatic Paget disease of bone.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 15 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 15 mg are equivalent for the purposes of substitution.

8208B *NP*	Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL	1	..	..	250.10	35.40	[a]	Aredia 15 mg	NV
8461H *NP*	Concentrated injection 15 mg in 5 mL	4	..	..	*250.14	35.40	[a]	Pamisol	HH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	DISODIUM PAMIDRONATE **Authority required (STREAMLINED)** ***3256*** Symptomatic Paget disease of bone. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.								
8209C *NP*	Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL	1	..	..	250.10	35.40	a	Aredia 30 mg	NV
8462J *NP*	Concentrated injection 30 mg in 10 mL	2	..	..	*250.12	35.40	a	Pamisol	HH
	DISODIUM PAMIDRONATE **Authority required (STREAMLINED)** ***3256*** Symptomatic Paget disease of bone. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8463K *NP*	Concentrated injection 60 mg in 10 mL	1	..	..	250.10	35.40		Pamisol	HH
	IBANDRONIC ACID **Restricted benefit** Bone metastases from breast cancer. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9357L *NP*	Tablet 50 mg (as ibandronate sodium monohydrate)	28	2	..	342.34	35.40		Bondronat	HH
	RISEDRONATE SODIUM **Authority required (STREAMLINED)** ***3070*** Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. **Authority required (STREAMLINED)** ***2645*** Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. **Authority required (STREAMLINED)** ***2646*** Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
	Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
8481J *NP*	Tablet 5 mg	28	5	..	46.55	35.40		Actonel	SW
8621R *NP*	Tablet 35 mg	4	5	..	46.55	35.40	[a]	Acris Once-a-Week	AF
							[a]	Actonel Once-a-Week	SW
							[a]	APO-Risedronate	TX
							[a]	Chem mart Risedronate	CH
							[a]	Risedronate-GA	GM
							[a]	Risedronate Sandoz	SZ
							[a]	Risedro once a week	QA
							[a]	Terry White Chemists Risedronate	TW
8972F *NP*	Tablet 35 mg (enteric coated)	4	5	..	46.55	35.40		Actonel EC	SW
9391G *NP*	Tablet 150 mg	1	5	..	49.53	35.40		Actonel Once-a-Month	SW
	RISEDRONATE SODIUM **Authority required (STREAMLINED)** ***3256*** Symptomatic Paget disease of bone.								
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8482K *NP*	Tablet 30 mg	28	1	..	259.79	35.40		Actonel	SW
	SODIUM CLODRONATE TETRAHYDRATE **Restricted benefit** Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy; Multiple myeloma; Bone metastases from breast cancer.								
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8132B *NP*	Capsule equivalent to 400 mg sodium clodronate	100	2	..	334.08	35.40		Bonefos	BN
8265B *NP*	Tablet equivalent to 800 mg sodium clodronate	60	2	..	391.44	35.40		Bonefos 800 mg	BN
	TILUDRONATE DISODIUM **Authority required (STREAMLINED)** ***3256*** Symptomatic Paget disease of bone.								
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
8267D *NP*	Tablet equivalent to 200 mg tiludronic acid	56	2	..	304.62	35.40	Skelid	SW

ZOLEDRONIC ACID

Authority required (STREAMLINED)

3945

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Only 1 treatment each year per patient will be PBS-subsidised.

Authority required (STREAMLINED)

3947

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Only 1 treatment each year per patient will be PBS-subsidised.

Authority required (STREAMLINED)

3946

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in a patient with fracture due to minimal trauma.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

In all cases, the fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

Only 1 treatment each year per patient will be PBS-subsidised.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9288W	Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL	1	..	..	589.17	35.40	Aclasta	NV

ZOLEDRONIC ACID

Authority required

Symptomatic Paget disease of bone.

Only 1 treatment each year per patient will be PBS-subsidised.

9350D	Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL	1	..	..	589.17	35.40	Aclasta	NV

Bisphosphonates, combinations

ALENDRONATE SODIUM with COLECALCIFEROL

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

3933

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
	Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
	Note Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.								
9012H *NP*	Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol	4	5	..	45.16	35.40		Fosamax Plus	MK

ALENDRONATE SODIUM with COLECALCIFEROL

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

3933

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9183H *NP*	Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol	4	5	..	45.16	35.40	[a]	Dronalen Plus	GM
				[B]2.50	47.66	35.40	[a]	Fosamax Plus 70 mg/140 mcg	MK

ALENDRONATE SODIUM with COLECALCIFEROL and CALCIUM CARBONATE

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

3933

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
	Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
9351E *NP*	Pack containing 4 tablets containing the equivalent of 70 mg alendronic acid with 140 micrograms colecalciferol and 48 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	‡1	5	..	45.16	35.40	[a]	Dronalen Plus D-Cal	FR
							[a]	Fosamax Plus D-Cal	MK
	DISODIUM ETIDRONATE and CALCIUM CARBONATE **Authority required (STREAMLINED)** ***2646*** Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
	Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
	Note No applications for increased maximum quantities and/or repeats will be authorised.								
8056B *NP*	Pack containing 28 tablets disodium etidronate 200 mg and 76 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	‡1	1	..	70.69	35.40		Didrocal	PF
	RISEDRONATE SODIUM and CALCIUM CARBONATE **Authority required (STREAMLINED)** ***3070*** Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.								
	Authority required (STREAMLINED) ***2645*** Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.								
	Authority required (STREAMLINED) ***2646*** Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
	Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
8899J *NP*	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	‡1	5	..	46.55	35.40	[a]	Acris Combi	AF
							[a]	Actonel Combi	SW
8973G *NP*	Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets	‡1	5	..	46.55	35.40		Actonel EC Combi	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	calcium carbonate 1.25 g (equivalent to 500 mg calcium)								

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8974H *NP*	Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms	‡1	5	..	46.55	35.40		Actonel EC Combi D	SW
9147K *NP*	Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms	‡1	5	..	46.55	35.40		Actonel Combi D	SW

Other drugs affecting bone structure and mineralization

CALCITRIOL

Authority required (STREAMLINED)

1165

Hypocalcaemia due to renal disease;

1166

Hypoparathyroidism;

1167

Hypophosphataemic rickets;

1467

Vitamin D-resistant rickets;

2636

Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

2502Q *NP*	Capsule 0.25 microgram	100	3	..	37.31	35.40	[a]	Calciprox	GN
							[a]	Calcitriol-GA	GM
							[a]	Calcitriol-PS	FZ
							[a]	Calcitriol Sandoz	SZ
							[a]	GenRx Calcitriol	GX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
						[a]	Kosteo	QA
						[a]	Rocaltrol	RO
						[a]	Sical	AF

DENOSUMAB

Authority required

Bone metastases from breast cancer;

Bone metastases from hormone-resistant prostate cancer.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5110Y *NP*	Injection 120 mg in 1.7 mL	1	5	..	531.97	35.40	Xgeva	AN

DENOSUMAB

Authority required (STREAMLINED)

2758

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a woman aged 70 years or older with a bone mineral density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated;

3987

Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in a woman with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5457F *NP*	Injection 60 mg in 1 mL pre-filled syringe	1	..	..	304.87	35.40	Prolia	AN

RALOXIFENE HYDROCHLORIDE

Authority required (STREAMLINED)

2647

Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8363E *NP*	Tablet 60 mg	28	5	..	57.87	35.40	Evista	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	STRONTIUM RANELATE							
	Authority required (STREAMLINED)							
	2758							
	Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a woman aged 70 years or older with a bone mineral density (BMD) T-score of -3.0 or less.							
	The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.							
	Authority required (STREAMLINED)							
	2647							
	Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.							
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.							
	Note							
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
3036T *NP*	Sachet containing granules for oral suspension 2 g	28	5	..	53.34	35.40	Protos 2 g	SE
	TERIPARATIDE							
	Note							
	Any queries concerning the arrangements to prescribe teriparatide may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written applications for authority to prescribe teriparatide should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
	Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.							
	Authority required							
	Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who: (a) has a bone mineral density (BMD) T-score of -3.0 or less; and (b) has had 2 or more fractures due to minimal trauma; and (c) has experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses.							
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.							
	If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided at the time of application.							
	If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details of accepted toxicities including severity can be found on the Medicare Australia website at www.medicareaustralia.gov.au and must be provided at the time of application.							
	Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, disodium etidronate 200 mg with calcium carbonate 1.25 g per day, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.							
	Authority applications must be made in writing and must include: Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed during the course of anti-resorptive therapy and the score of the qualifying BMD measurement.							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							

Musculo-skeletal system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Authority required Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who was receiving treatment with teriparatide prior to 1 May 2009. The authority application must be made in writing and the commencement date of treatment and the number of doses the patient has received of teriparatide must be provided with the application. The patient is eligible to receive a maximum of 18 months therapy of combined PBS-subsidised and non-PBS-subsidised therapy. Patients may qualify for PBS-subsidised treatment under this restriction once only. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Authority required** Continuing treatment for severe established osteoporosis where the patient has previously been issued with an authority prescription for this drug. Teriparatide must only be used for a lifetime maximum of 18 months therapy (18 pens). Up to a maximum of 18 pens will be reimbursed through the PBS. Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** Special Pricing Arrangements apply.							
9411H	Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen	1	5	..	438.37	35.40	Forteo	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Nervous system

Analgesics

Opioids

Natural opium alkaloids

CODEINE PHOSPHATE

1214X *NP*	Tablet 30 mg	20	..	..	16.87	17.96		Fawns and McAllan Proprietary Limited	FM

CODEINE PHOSPHATE with PARACETAMOL

Note

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol below.

1215Y *NP*	Tablet 30 mg-500 mg	20	..	..	7.48	8.57	a	APO-Paracetamol/Codeine 500/30	TX
							a	Codalgin Forte	FM
							a	Codapane Forte	AL
							a	Comfarol Forte	SZ
							a	Prodeine Forte	AV
				B1.88	9.36	8.57	a	Panadeine Forte	SW

CODEINE PHOSPHATE with PARACETAMOL

Authority required

Severe disabling pain not responding to non-narcotic analgesics.

Note

Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

8785J *NP*	Tablet 30 mg-500 mg	60	..	..	*9.60	10.69	a	APO-Paracetamol/Codeine 500/30	TX
							a	Codalgin Forte	FM
							a	Codapane Forte	AL
							a	Comfarol Forte	SZ
							a	Prodeine Forte	AV
				B5.64	*15.24	10.69	a	Panadeine Forte	SW

HYDROMORPHONE HYDROCHLORIDE

Caution

The risk of drug dependence is high.

8420E *NP*	Injection 2 mg in 1 mL	5	..	..	22.84	23.93		Dilaudid	MF
8421F *NP*	Injection 10 mg in 1 mL	5	..	..	28.97	30.06		Dilaudid-HP	MF
8422G *NP*	Injection 50 mg in 5 mL	5	..	..	52.00	35.40		Dilaudid-HP	MF
8423H *NP*	Injection 500 mg in 50 mL	1	..	..	75.41	35.40		Dilaudid-HP	MF

HYDROMORPHONE HYDROCHLORIDE

Caution

The risk of drug dependence is high.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Restricted benefit Chronic severe disabling pain not responding to non-narcotic analgesics. **Note** Authorities for increased maximum quantities and/or repeats will be granted only for: (i) chronic severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
9299K *NP*	Tablet 4 mg (modified release)	14	..	..	30.95	32.04	Jurnista	JC
9406C *NP*	Tablet 8 mg (modified release)	14	..	..	36.41	35.40	Jurnista	JC
9407D *NP*	Tablet 16 mg (modified release)	14	..	..	52.82	35.40	Jurnista	JC
9408E *NP*	Tablet 32 mg (modified release)	14	..	..	88.70	35.40	Jurnista	JC
9409F *NP*	Tablet 64 mg (modified release)	14	..	..	149.38	35.40	Jurnista	JC
	HYDROMORPHONE HYDROCHLORIDE **Caution** The risk of drug dependence is high. **Restricted benefit** Severe disabling pain not responding to non-narcotic analgesics. **Note** Authorities for increased maximum quantities and/or repeats will be granted only for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
8424J *NP*	Oral liquid 1 mg per mL, 473 mL	1	..	..	63.70	35.40	Dilaudid	MF
8541M *NP*	Tablet 2 mg	20	..	..	17.10	18.19	Dilaudid	MF
8542N *NP*	Tablet 4 mg	20	..	..	19.85	20.94	Dilaudid	MF
8543P *NP*	Tablet 8 mg	20	..	..	30.03	31.12	Dilaudid	MF
	MORPHINE HYDROCHLORIDE **Caution** The risk of drug dependence is high. **Restricted benefit** Severe disabling pain not responding to non-narcotic analgesics.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Authorities for increased maximum quantities and/or repeats will be granted only for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
2122Q *NP*	Oral solution 2 mg per mL, 200 mL	1	..	..	20.33	21.42	Ordine 2	MF
2123R *NP*	Oral solution 5 mg per mL, 200 mL	1	..	..	22.73	23.82	Ordine 5	MF
2124T *NP*	Oral solution 10 mg per mL, 200 mL	1	..	..	26.86	27.95	Ordine 10	MF
	MORPHINE SULFATE **Caution** The risk of drug dependence is high.							
1644M *NP,MW*	Injection 10 mg in 1 mL	5	..	..	13.99	15.08	Hospira Pty Limited	HH
1645N *NP,MW*	Injection 15 mg in 1 mL	5	..	..	14.35	15.44	Hospira Pty Limited	HH
1647Q *NP*	Injection 30 mg in 1 mL	5	..	..	15.77	16.86	Hospira Pty Limited	HH
	MORPHINE SULFATE **Caution** The risk of drug dependence is high. **Restricted benefit** Severe disabling pain due to cancer not responding to non-narcotic analgesics.							
8669G *NP*	Tablet 10 mg	20	..	..	14.31	15.40	Sevredol	MF
8670H *NP*	Tablet 20 mg	20	..	..	15.26	16.35	Sevredol	MF
	MORPHINE SULFATE **Caution** The risk of drug dependence is high. **Restricted benefit** Severe disabling pain not responding to non-narcotic analgesics. **Note** Authorities for increased maximum quantities and/or repeats will be granted only for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	prescription for treatment beyond 12 months has previously been issued for this patient.								
1646P *NP*	Tablet 30 mg	20	..	..	14.03	15.12		Anamorph	FM

MORPHINE SULFATE

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

1653B *NP*	Tablet 10 mg (controlled release)	28	..	..	20.04	21.13	[a]	APOTEX-MORPHINE MR	TX
							[a]	Momex SR 10	QA
							[a]	MS Contin	MF
1654C *NP*	Tablet 30 mg (controlled release)	28	..	..	35.89	35.40	[a]	APOTEX-MORPHINE MR	TX
							[a]	Momex SR 30	QA
							[a]	MS Contin	MF
1655D *NP*	Tablet 60 mg (controlled release)	28	..	..	54.48	35.40	[a]	APOTEX-MORPHINE MR	TX
							[a]	Momex SR 60	QA
							[a]	MS Contin	MF
1656E *NP*	Tablet 100 mg (controlled release)	28	..	..	72.51	35.40	[a]	APOTEX-MORPHINE MR	TX
							[a]	Momex SR 100	QA
							[a]	MS Contin	MF
2839K *NP*	Capsule 20 mg (containing sustained release pellets)	20	..	..	20.47	21.56		Kapanol	GK
2840L *NP*	Capsule 50 mg (containing sustained release pellets)	20	..	..	33.54	34.63		Kapanol	GK
2841M *NP*	Capsule 100 mg (containing sustained release pellets)	20	..	..	53.46	35.40		Kapanol	GK
8035X *NP*	Tablet 5 mg (controlled release)	28	..	..	17.59	18.68		MS Contin	MF
8146R *NP*	Sachet containing controlled release granules for oral suspension, 30 mg per sachet	28	..	..	62.07	35.40		MS Contin Suspension 30 mg	MF
8305D *NP*	Sachet containing controlled release granules for oral suspension, 60 mg per sachet	28	..	..	69.87	35.40		MS Contin Suspension 60 mg	MF
8306E *NP*	Sachet containing controlled release granules for oral suspension, 100 mg per sachet	28	..	..	86.37	35.40		MS Contin Suspension 100 mg	MF
8349K *NP*	Capsule 10 mg (containing sustained release pellets)	20	..	..	16.92	18.01		Kapanol	GK
8489T *NP*	Tablet 15 mg (controlled release)	28	..	..	24.23	25.32		MS Contin	MF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
8490W *NP*	Sachet containing controlled release granules for oral suspension, 20 mg per sachet	28	..	..	60.29	35.40	MS Contin Suspension 20 mg	MF
8491X *NP*	Capsule 30 mg (controlled release)	14	..	..	24.22	25.31	MS Mono	MF
8492Y *NP*	Capsule 60 mg (controlled release)	14	..	..	35.87	35.40	MS Mono	MF
8493B *NP*	Capsule 90 mg (controlled release)	14	..	..	41.42	35.40	MS Mono	MF
8494C *NP*	Capsule 120 mg (controlled release)	14	..	..	54.47	35.40	MS Mono	MF

MORPHINE SULFATE

Caution

The risk of drug dependence is high.

Authority required

Chronic severe disabling pain due to cancer.

8453X *NP*	Tablet 200 mg (controlled release)	28	..	..	121.86	35.40	MS Contin	MF
8454Y *NP*	Sachet containing controlled release granules for oral suspension, 200 mg per sachet	28	..	..	163.75	35.40	MS Contin Suspension 200 mg	MF

MORPHINE TARTRATE

Caution

The risk of drug dependence is high.

1607N *NP*	Injection 120 mg in 1.5 mL	5	..	..	30.67	31.76	Hospira Pty Limited	HH

OXYCODONE

Caution

The risk of drug dependence is high.

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

2481N *NP*	Suppository 30 mg	12	..	..	43.66	35.40	Proladone	PL

OXYCODONE HYDROCHLORIDE

Caution

The risk of drug dependence is high.

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
2622B *NP*	Tablet 5 mg	20	..	..	12.30	13.39	Endone	QA
8464L *NP*	Capsule 5 mg	20	..	..	12.30	13.39	OxyNorm	MF
8501K *NP*	Capsule 10 mg	20	..	..	15.42	16.51	OxyNorm	MF
8502L *NP*	Capsule 20 mg	20	..	..	20.15	21.24	OxyNorm	MF
8644Y *NP*	Oral solution 5 mg per 5 mL, 250 mL	1	..	..	20.72	21.81	OxyNorm Liquid 5mg/5mL	MF
	OXYCODONE HYDROCHLORIDE **Caution** The risk of drug dependence is high. **Restricted benefit** Chronic severe disabling pain not responding to non-narcotic analgesics. **Note** Authorities for increased maximum quantities and/or repeats will be granted only for: (i) chronic severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
8385H *NP*	Tablet 10 mg (controlled release)	28	..	..	27.09	28.18	OxyContin	MF
8386J *NP*	Tablet 20 mg (controlled release)	28	..	..	40.97	35.40	OxyContin	MF
8387K *NP*	Tablet 40 mg (controlled release)	28	..	..	62.60	35.40	OxyContin	MF
8388L *NP*	Tablet 80 mg (controlled release)	28	..	..	96.72	35.40	OxyContin	MF
8681X *NP*	Tablet 5 mg (controlled release)	28	..	..	26.00	27.09	OxyContin	MF
9399Q *NP*	Tablet 15 mg (controlled release)	28	..	..	35.47	35.40	OxyContin	MF
9400R *NP*	Tablet 30 mg (controlled release)	28	..	..	52.69	35.40	OxyContin	MF
	OXYCODONE HYDROCHLORIDE with NALOXONE HYDROCHLORIDE **Caution** The risk of drug dependence is high. **Restricted benefit** Chronic severe disabling pain not responding to non-narcotic analgesics.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note Authorities for increased maximum quantities and/or repeats will be granted only for: (i) chronic severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8000C *NP*	Tablet 5 mg-2.5 mg (controlled release)	28	..	..	29.37	30.46		Targin 5/2.5mg	MF
8934F *NP*	Tablet 10 mg-5 mg (controlled release)	28	..	..	30.67	31.76		Targin 10/5mg	MF
8935G *NP*	Tablet 20 mg-10 mg (controlled release)	28	..	..	46.85	35.40		Targin 20/10mg	MF
8936H *NP*	Tablet 40 mg-20 mg (controlled release)	28	..	..	73.28	35.40		Targin 40/20mg	MF

Phenylpiperidine derivatives

FENTANYL

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 2.063 mg, fentanyl transdermal patch 1.28 mg and fentanyl transdermal patch 2.1 mg (all releasing approximately 12 micrograms per hour) are equivalent for the purposes of substitution.

5265D *NP*	Transdermal patch 1.28 mg (releasing approximately 12 micrograms per hour)	5	..	..	41.53	35.40	[a]	Denpax	AF
5437E *NP*	Transdermal patch 2.063 mg (releasing approximately 12 micrograms per hour)	5	..	..	41.53	35.40	[a]	Fenpatch 12	ZP
8878G *NP*	Transdermal patch 2.1 mg (releasing approximately 12 micrograms per hour)	5	..	..	41.53	35.40	[a]	Durogesic 12	JC
							[a]	Fentanyl Sandoz	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	FENTANYL								
	Caution								
	The risk of drug dependence is high.								
	Restricted benefit								
	Chronic severe disabling pain not responding to non-narcotic analgesics.								
	Note								
	Authorities for increased maximum quantities and/or repeats will be granted only for: (i) chronic severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.								
	Note								
	Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour). Pharmaceutical benefits that have the forms fentanyl transdermal patch 4.125 mg, fentanyl transdermal patch 2.55 mg and fentanyl transdermal patch 4.2 mg (all releasing approximately 25 micrograms per hour) are equivalent for the purposes of substitution.								
5277R *NP*	Transdermal patch 2.55 mg (releasing approximately 25 micrograms per hour)	5	..	..	49.46	35.40	[a]	Denpax	AF
5438F *NP*	Transdermal patch 4.125 mg (releasing approximately 25 micrograms per hour)	5	..	..	49.46	35.40	[a]	Fenpatch 25	ZP
8891Y *NP*	Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour)	5	..	..	49.46	35.40	[a]	Durogesic 25	JC
							[a]	Fentanyl Sandoz	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	FENTANYL								
	Caution								
	The risk of drug dependence is high.								
	Restricted benefit								
	Chronic severe disabling pain not responding to non-narcotic analgesics.								
	Note								
	Authorities for increased maximum quantities and/or repeats will be granted only for: (i) chronic severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.								
	Note								
	Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour). Pharmaceutical benefits that have the forms fentanyl transdermal patch 8.25 mg, fentanyl transdermal patch 5.10 mg and fentanyl transdermal patch 8.4 mg (all releasing approximately 50 micrograms per hour) are equivalent for the purposes of substitution.								
5278T *NP*	Transdermal patch 5.10 mg (releasing approximately 50 micrograms per hour)	5	..	..	81.58	35.40	[a]	Denpax	AF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
5439G *NP*	Transdermal patch 8.25 mg (releasing approximately 50 micrograms per hour)	5	..	..	81.58	35.40	a	Fenpatch 50	ZP
8892B *NP*	Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour)	5	..	..	81.58	35.40	a	Durogesic 50	JC
							a	Fentanyl Sandoz	SZ

FENTANYL

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 12.375 mg, fentanyl transdermal patch 7.65 mg and fentanyl transdermal patch 12.6 mg (all releasing approximately 75 micrograms per hour) are equivalent for the purposes of substitution.

5279W *NP*	Transdermal patch 7.65 mg (releasing approximately 75 micrograms per hour)	5	..	..	108.37	35.40	a	Denpax	AF
5440H *NP*	Transdermal patch 12.375 mg (releasing approximately 75 micrograms per hour)	5	..	..	108.37	35.40	a	Fenpatch 75	ZP
8893C *NP*	Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour)	5	..	..	108.37	35.40	a	Durogesic 75	JC
							a	Fentanyl Sandoz	SZ

FENTANYL

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour). Pharmaceutical benefits that have the forms fentanyl transdermal patch 16.5 mg, fentanyl transdermal patch 10.20 mg and fentanyl transdermal patch 16.8 mg (all releasing approximately 100 micrograms per hour) are equivalent for the purposes of substitution.								
5280X *NP*	Transdermal patch 10.20 mg (releasing approximately 100 micrograms per hour)	5	..	..	132.30	35.40	[a]	Denpax	AF
5441J *NP*	Transdermal patch 16.5 mg (releasing approximately 100 micrograms per hour)	5	..	..	132.30	35.40	[a]	Fenpatch 100	ZP
8894D *NP*	Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour)	5	..	..	132.30	35.40	[a]	Durogesic 100	JC
							[a]	Fentanyl Sandoz	SZ

Diphenylpropylamine derivatives

METHADONE HYDROCHLORIDE

Caution

The risk of drug dependence is high.

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1606M *NP*	Injection 10 mg in 1 mL	5	..	..	49.31	35.40		Physeptone	QA
1609Q *NP*	Tablet 10 mg	20	..	..	15.23	16.32		Physeptone	QA

Oripavine derivatives

BUPRENORPHINE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
	Caution The risk of drug dependence is high.								
8865N *NP*	Transdermal patch 5 mg (releasing approximately 5 micrograms per hour)	2	..	..	26.70	27.79		Norspan	MF
8866P *NP*	Transdermal patch 10 mg (releasing approximately 10 micrograms per hour)	2	..	..	40.77	35.40		Norspan	MF
8867Q *NP*	Transdermal patch 20 mg (releasing approximately 20 micrograms per hour)	2	..	..	56.08	35.40		Norspan	MF

Other opioids

TRAMADOL HYDROCHLORIDE
Restricted benefit
For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

8455B *NP*	Capsule 50 mg	20	..	..	8.39	9.48	[a]	APO-Tramadol	TX
							[a]	Chem mart Tramadol	CH
							[a]	GA Tramadol 50mg	GM
							[a]	GenRx Tramadol	GX
							[a]	Lodam 50	ZP
							[a]	Terry White Chemists Tramadol	TW
							[a]	Tramadol Sandoz	SZ
							[a]	Tramedo	AF
							[a]	Zydol	QA
				[B]1.83	10.22	9.48	[a]	Tramal	CS

TRAMADOL HYDROCHLORIDE
Restricted benefit
For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

8611F *NP*	Capsule 50 mg	20	2	..	8.39	9.48	[a]	APO-Tramadol	TX
							[a]	Chem mart Tramadol	CH
							[a]	GA Tramadol 50mg	GM
							[a]	GenRx Tramadol	GX
							[a]	Lodam 50	ZP
							[a]	Terry White Chemists Tramadol	TW
							[a]	Tramadol Sandoz	SZ
							[a]	Tramedo	AF
							[a]	Zydol	QA
				[B]1.83	10.22	9.48	[a]	Tramal	CS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	TRAMADOL HYDROCHLORIDE								
	Restricted benefit								
	For pain where aspirin and/or paracetamol alone are inappropriate or have failed.								
	Note								
	Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics.								
2527B *NP*	Tablet 50 mg (twice daily sustained release)	20	..	..	10.16	11.25		Tramal SR 50	CS
8523N *NP*	Tablet 100 mg (twice daily sustained release)	20	..	..	11.76	12.85	a	APO-Tramadol SR	TX
							a	Chem mart Tramadol SR	CH
							a	GA Tramadol SR 100mg	GM
							a	Lodam SR 100	ZP
							a	Terry White Chemists Tramadol SR	TW
							a	Tramadol Sandoz SR	SZ
							a	Tramedo SR 100	AF
							a	Zydol SR 100	QA
				B3.40	15.16	12.85	a	Tramal SR 100	CS
8524P *NP*	Tablet 150 mg (twice daily sustained release)	20	..	..	13.62	14.71	a	APO-Tramadol SR	TX
							a	Chem mart Tramadol SR	CH
							a	GA Tramadol SR 150mg	GM
							a	Lodam SR 150	ZP
							a	Terry White Chemists Tramadol SR	TW
							a	Tramadol Sandoz SR	SZ
							a	Tramedo SR 150	AF
							a	Zydol SR 150	QA
				B4.06	17.68	14.71	a	Tramal SR 150	CS
8525Q *NP*	Tablet 200 mg (twice daily sustained release)	20	..	..	15.18	16.27	a	APO-Tramadol SR	TX
							a	Chem mart Tramadol SR	CH
							a	GA Tramadol SR 200mg	GM
							a	Lodam SR 200	ZP
							a	Terry White Chemists Tramadol SR	TW
							a	Tramadol Sandoz SR	SZ
							a	Tramedo SR 200	AF
							a	Zydol SR 200	QA
				B4.59	19.77	16.27	a	Tramal SR 200	CS
8843K *NP*	Oral drops 100 mg per mL, 10 mL	‡1	..	..	13.71	14.80		Tramal	CS
9199E *NP*	Tablet 100 mg (once a day extended release)	10	..	..	11.41	12.50		Durotram XR	IA
9200F *NP*	Tablet 200 mg (once a day extended release)	10	..	..	13.55	14.64		Durotram XR	IA
9201G *NP*	Tablet 300 mg (once a day extended release)	10	..	..	16.02	17.11		Durotram XR	IA

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	TRAMADOL HYDROCHLORIDE **Restricted benefit** Short-term treatment of acute pain. **Note** No applications for increased maximum quantities and/or repeats will be authorised.								
8582Q *NP*	Injection 100 mg in 2 mL	5	..	..	13.10	14.19	[a]	Tramahexal	SZ
							[a]	Tramal 100	CS

Other analgesics and antipyretics

Salicylic acid and derivatives

	ASPIRIN								
1010E *NP*	Tablet 300 mg (dispersible)	96	1	..	8.50	9.59		Solprin	RC

Anilides

	PARACETAMOL								
1746X *NP*	Tablet 500 mg	100	1	..	8.32	9.41	[a]	APO-Paracetamol	TX
							[a]	Chem mart Paracetamol	XS
							[a]	Febridol	GM
							[a]	Generic Health Pty Ltd	GQ
							[a]	Panamax	SW
							[a]	Paracetamol Sandoz	SZ
							[a]	Paralgin	FM
							[a]	Pharmacy Choice Paracetamol	YM
							[a]	Terry White Chemists Paracetamol	YS
1747Y *NP*	Oral liquid 120 mg per 5 mL, 100 mL	‡1	2	..	9.38	10.47		Panamax	SW
1770E *NP*	Oral liquid 240 mg per 5 mL, 200 mL	‡1	2	..	10.68	11.77		Panamax 240 Elixir	SW

	PARACETAMOL **Restricted benefit** Chronic arthropathies.								
8784H *NP*	Tablet 500 mg	300	4	..	*12.12	13.21	[a]	APO-Paracetamol	TX
							[a]	Chem mart Paracetamol	XS
							[a]	Febridol	GM
							[a]	Generic Health Pty Ltd	GQ
							[a]	Panamax	SW
							[a]	Paracetamol Sandoz	SZ
							[a]	Paralgin	FM
							[a]	Pharmacy Choice Paracetamol	YM
							[a]	Terry White Chemists Paracetamol	YS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	PARACETAMOL							
	Restricted benefit							
	Relief of persistent pain associated with osteoarthritis.							
8814X *NP*	Tablet 665 mg (modified release)	192	5	..	*16.64	17.73	Panadol Osteo	GC

Antimigraine preparations

Ergot alkaloids

	DIHYDROERGOTAMINE MESYLATE							
1323P	Injection 1 mg in 1 mL	5	..	..	17.06	18.15	Dihydergot	NV
	METHYSERGIDE							
	Note							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2826R *NP*	Tablet 1 mg	100	2	..	*44.96	35.40	Deseril	LM

Selective 5HT $_1$ -receptor agonists

	ELETRIPTAN							
	Caution							
	Eletriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.							
	Authority required (STREAMLINED)							
	3233							
	Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics.							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Note							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5290K *NP*	Tablet 40 mg (as hydrobromide)	4	5	..	24.75	25.84	Relpax	PF
5291L *NP*	Tablet 80 mg (as hydrobromide)	4	5	..	24.75	25.84	Relpax	PF
	RIZATRIPTAN							
	Caution							
	Rizatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.							
	Authority required (STREAMLINED)							
	3233							
	Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics.							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Note							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9313E *NP*	Wafer 10 mg (as benzoate)	4	5	..	*25.12	26.21	Maxalt	MK
	SUMATRIPTAN							
	Caution							
	Sumatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Authority required (STREAMLINED)								
	3233								
	Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
	Note								
	Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.								
8144P *NP*	Tablet 50 mg (as succinate)	4	5	..	24.38	25.47	[a]	Pharmacor Sumatriptan 50	CR
							[a]	Sumatriptan-GA	GM
							[a]	Sumatriptan generichealth	GQ
				..	*24.38	25.47	[a]	APO-Sumatriptan	TX
							[a]	Chem mart Sumatriptan	CH
							[a]	Sumagran 50	QA
							[a]	Sumatab	AF
							[a]	Terry White Chemists Sumatriptan	TW
				[B]1.84	*26.22	25.47	[a]	Imigran	GK
8885P *NP*	Tablet (fast disintegrating) 50 mg (as succinate)	4	5	..	*24.38	25.47	[a]	Imigran FDT	GK

SUMATRIPTAN

Caution

Sumatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Authority required (STREAMLINED)

3233

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8341B *NP*	Nasal spray 20 mg in 0.1 mL single dose unit	2	5	..	19.25	20.34		Imigran	GK

Other antimigraine preparations

CYPROHEPTADINE HYDROCHLORIDE

Restricted benefit

Prevention of migraine.

Note

Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1798P *NP*	Tablet 4 mg	100	2	..	14.19	15.28		Periactin	AS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	PIZOTIFEN MALATE							
	Note							
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
3074T *NP*	Tablet 500 micrograms (base)	100	2	..	21.75	22.84	Sandomigran 0.5	NV

Antiepileptics

Antiepileptics

Barbiturates and derivatives

PHENOBARBITONE
Restricted benefit
Epilepsy.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1850J *NP*	Tablet 30 mg	200	4	..	16.60	17.69	Aspen Pharma Pty Ltd	QA

PHENOBARBITONE SODIUM
Restricted benefit
Epilepsy.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1853M *NP*	Injection 200 mg in 1 mL	5	..	..	39.02	35.40	Fawns and McAllan Proprietary Limited	FM

PRIMIDONE
Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1939C *NP*	Tablet 250 mg	200	2	..	83.49	35.40	Mysoline	LM

Hydantoin derivatives

PHENYTOIN
Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1249R *NP*	Tablet 50 mg	200	2	..	43.56	35.40	Dilantin Infatabs	PF
2692Q *NP*	Paediatric oral suspension 30 mg per 5 mL, 500 mL	‡1	3	..	26.40	27.49	Dilantin	PF

PHENYTOIN SODIUM
Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1873N *NP*	Capsule 30 mg	200	2	..	29.18	30.27	Dilantin Sodium	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
1874P *NP*	Capsule 100 mg	200	2	..	30.12	31.21		Dilantin Sodium	PF

Succinimide derivatives

ETHOSUXIMIDE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1413J *NP*	Capsule 250 mg	200	2	..	54.10	35.40		Zarontin	PF
1414K *NP*	Paediatric syrup 250 mg per 5 mL, 200 mL	‡1	5	..	25.29	26.38		Zarontin	PF

Benzodiazepine derivatives

CLONAZEPAM

Authority required

Neurologically proven epilepsy.

Caution

Abuse of clonazepam has been reported. Refer to the current product information.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1805B *NP*	Tablet 500 micrograms	200	2	..	*19.50	20.59	[a]	Paxam 0.5	AF
				[B]3.42	*22.92	20.59	[a]	Rivotril	RO
1806C *NP*	Tablet 2 mg	200	2	..	*31.06	32.15	[a]	Paxam 2	AF
				[B]3.86	*34.92	32.15	[a]	Rivotril	RO
1808E *NP*	Oral liquid 2.5 mg per mL, 10 mL	2	..	..	*15.04	16.13		Rivotril	RO

CLONAZEPAM

Restricted benefit

Epilepsy.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1807D *NP*	Injection 1 mg in 2 mL (set containing solution 1 mg in 1 mL and 1 mL diluent)	5	..	..	18.58	19.67		Rivotril	RO

NITRAZEPAM

Authority required

Myoclonic epilepsy;

Malignant neoplasia (late stage);

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2732T	Tablet 5 mg	50	5	..	*9.22	10.31	[a]	Alodorm	AF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP				[B]2.90	*12.12	10.31	[a]	Mogadon	VT

Carboxamide derivatives

CARBAMAZEPINE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2419H *NP*	Tablet 200 mg	200	2	[B]2.96	*31.96	30.09	[a]	Tegretol 200	NV
				..	29.02	30.11	[a]	Carbamazepine Sandoz	SZ
							[a]	Teril	AF
2422L *NP*	Tablet 100 mg	200	2	[B]2.96	*21.46	19.59	[a]	Tegretol 100	NV
				..	18.51	19.60	[a]	Carbamazepine Sandoz	SZ
2426Q *NP*	Tablet 200 mg (controlled release)	200	2	..	29.48	30.57		Tegretol CR 200	NV
2427R *NP*	Oral suspension 100 mg per 5 mL, 300 mL	‡1	5	..	21.35	22.44		Tegretol Liquid	NV
2431Y *NP*	Tablet 400 mg (controlled release)	200	2	..	49.02	35.40		Tegretol CR 400	NV

OXCARBAZEPINE

Authority required (STREAMLINED)

1587

Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8584T *NP*	Tablet 150 mg	100	5	..	72.27	35.40		Trileptal	NV
8585W *NP*	Tablet 300 mg	100	5	..	115.08	35.40		Trileptal	NV
8586X *NP*	Tablet 600 mg	100	5	..	187.98	35.40		Trileptal	NV
8588B *NP*	Oral suspension 60 mg per mL, 250 mL	2	5	..	*138.12	35.40		Trileptal	NV

Fatty acid derivatives

SODIUM VALPROATE

Caution

There are reports of fatal hepatotoxicity, particularly in children.
There is increasing evidence of dose-related teratogenesis from this drug.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2289L *NP*	Tablet 200 mg (enteric coated)	200	2	..	*29.92	31.01	[a]	Sodium Valproate Sandoz	SZ
							[a]	Valprease 200	QA
							[a]	Valpro 200	AF
							[a]	Valproate Winthrop EC 200	WA
				[B]2.00	*31.92	31.01	[a]	Epilim EC	SW
2290M *NP*	Tablet 500 mg (enteric coated)	200	2	..	*51.38	35.40	[a]	Sodium Valproate Sandoz	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Valprease 500	QA
							[a]	Valpro 500	AF
							[a]	Valproate Winthrop EC 500	WA
				[B]2.00	*53.38	35.40	[a]	Epilim EC	SW
2293Q *NP*	Oral liquid 200 mg per 5 mL, 300 mL	2	2	..	*34.92	35.40		Epilim Liquid	SW
2294R *NP*	Crushable tablet 100 mg	200	2	..	*32.00	33.09		Epilim	SW
2295T *NP*	Syrup 200 mg per 5 mL, 300 mL	2	2	..	*34.92	35.40		Epilim Syrup	SW

TIAGABINE HYDROCHLORIDE

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8221Q *NP*	Tablet 5 mg (base)	100	5	..	*72.64	35.40		Gabitril	OA
8222R *NP*	Tablet 10 mg (base)	100	5	..	*138.84	35.40		Gabitril	OA
8223T *NP*	Tablet 15 mg (base)	100	5	..	*196.88	35.40		Gabitril	OA

VIGABATRIN

Caution

Visual field defects have been reported with this drug.

Authority required (STREAMLINED)

1426

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2667J *NP*	Tablet 500 mg	100	5	..	100.93	35.40		Sabril	SW
2668K *NP*	Oral powder, sachet 500 mg	60	5	..	67.70	35.40		Sabril	SW

Other antiepileptics

GABAPENTIN

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1834M *NP*	Capsule 300 mg	100	5	..	45.09	35.40	[a]	DBL Gabapentin	HH
							[a]	Gabapentin 300	CR
							[a]	Gabapentin-GA	GM
							[a]	Gabapentin Sandoz	SZ
							[a]	Gabatine 300	QA
							[a]	Gantin	GN
							[a]	GenRx Gabapentin	GX

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Nupentin 300	AF
				[B]0.61	45.70	35.40	[a]	Neurontin	PF
1835N *NP*	Capsule 400 mg	100	5	..	57.68	35.40	[a]	DBL Gabapentin	HH
							[a]	Gabapentin 400	CR
							[a]	Gabapentin Sandoz	SZ
							[a]	Gabatine 400	QA
							[a]	Gantin	GN
							[a]	GenRx Gabapentin	GX
							[a]	Nupentin 400	AF
				[B]0.68	58.36	35.40	[a]	Neurontin	PF
8389M *NP*	Tablet 800 mg	100	5	..	114.90	35.40	[a]	Gabaran	RA
							[a]	Gabatine 800	QA
							[a]	Gantin	GN
							[a]	GenRx Gabapentin	GX
							[a]	Nupentin Tabs	AF
							[a]	Pharmacor Gabapentin 800	CR
				[B]0.67	115.57	35.40	[a]	Neurontin	PF
8505P *NP*	Capsule 100 mg	100	5	..	18.18	19.27	[a]	APO-Gabapentin	TX
							[a]	DBL Gabapentin	HH
							[a]	Gabatine 100	QA
							[a]	Nupentin 100	AF
				[B]0.68	18.86	19.27	[a]	Neurontin	PF
8559L *NP*	Tablet 600 mg	100	5	..	87.79	35.40	[a]	Gabaran	RA
							[a]	Gabatine 600	QA
							[a]	GenRx Gabapentin	GX
							[a]	Nupentin Tabs	AF
							[a]	Pharmacor Gabapentin 600	CR
				[B]0.68	88.47	35.40	[a]	Neurontin	PF

LACOSAMIDE

Authority required

Treatment, initiated by a neurologist, in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs in a patient aged 16 years or older with intractable epilepsy.

A patient must have trialled and failed to achieve satisfactory seizure control with:
(i) at least one first-line anti-epileptic agent; and
(ii) at least two second-line adjunctive anti-epileptic agents;

Continuing treatment, in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, of partial epileptic seizures in a patient aged 16 years or older, who has previously been treated with PBS-subsidised lacosamide.

Note

No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9333F *NP*	Tablet 50 mg	14	1	..	30.21	31.30	Vimpat	UC
9334G *NP*	Tablets 100 mg, 14	‡1	1	..	52.29	35.40	Vimpat	UC
9335H *NP*	Tablet 100 mg	56	5	..	188.45	35.40	Vimpat	UC
9336J	Tablets 150 mg, 14	‡1	1	..	74.69	35.40	Vimpat	UC

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP									
9337K	Tablet 150 mg	56	5	..	272.64	35.40		Vimpat	UC
NP									
9338L	Tablet 200 mg	56	5	..	355.38	35.40		Vimpat	UC
NP									

LAMOTRIGINE

Authority required (STREAMLINED)

1426

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2848X	Tablet 25 mg	56	5	..	23.68	24.77	a	APO-Lamotrigine	TX
NP									
							a	GenRx Lamotrigine	GX
							a	Lamidus	RA
							a	Lamogine	AF
							a	Lamotrigine-GA	GN
							a	Lamotrigine generichealth	GQ
							a	Lamotrigine-PS	FZ
							a	Lamotrigine Sandoz	SZ
							a	Lamotrust 25	MI
							a	Seaze 25	QA
							a	Torlemo DT 25	TA
				B1.86	25.54	24.77	a	Lamictal	GK
2849Y	Tablet 50 mg	56	5	..	35.20	35.40	a	APO-Lamotrigine	TX
NP									
							a	GenRx Lamotrigine	GX
							a	Lamidus	RA
							a	Lamogine	AF
							a	Lamotrigine-GA	GN
							a	Lamotrigine generichealth	GQ
							a	Lamotrigine-PS	FZ
							a	Lamotrigine Sandoz	SZ
							a	Lamotrust 50	MI
							a	Seaze 50	QA
							a	Torlemo DT 50	TA
				B2.14	37.34	35.40	a	Lamictal	GK
2850B	Tablet 100 mg	56	5	..	52.62	35.40	a	APO-Lamotrigine	TX
NP									
							a	GenRx Lamotrigine	GX
							a	Lamidus	RA
							a	Lamogine	AF
							a	Lamotrigine-GA	GN
							a	Lamotrigine generichealth	GQ
							a	Lamotrigine-PS	FZ
							a	Lamotrigine Sandoz	SZ
							a	Lamotrust 100	MI
							a	Seaze 100	QA
							a	Torlemo DT 100	TA
				B1.69	54.31	35.40	a	Lamictal	GK

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
2851C	Tablet 200 mg	56	5	..	83.48	35.40	a	APO-Lamotrigine	TX
NP							a	GenRx Lamotrigine	GX
							a	Lamidus	RA
							a	Lamogine	AF
							a	Lamotrigine-GA	GN
							a	Lamotrigine generichealth	GQ
							a	Lamotrigine-PS	FZ
							a	Lamotrigine Sandoz	SZ
							a	Lamotrust 200	MI
							a	Seaze 200	QA
							a	Torlemo DT 200	TA
				B1.85	85.33	35.40	a	Lamictal	GK
8063J	Tablet 5 mg	56	5	..	14.17	15.26	a	Lamogine	AF
NP							a	Seaze 5	QA
				B1.85	16.02	15.26	a	Lamictal	GK

LEVETIRACETAM

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8654L	Tablet 250 mg	60	5	..	54.57	35.40	a	APO-Levetiracetam	TX
NP							a	Chem mart Levetiracetam	CH
							a	Kepcet	GM
							a	Keppra	UC
							a	Kevtam	AF
							a	Levecetam 250	RZ
							a	Levetiracetam generichealth	GQ
							a	Levetiracetam SZ	SZ
							a	Levitaccord	RA
							a	Levitam 250	QA
							a	Terry White Chemists Levetiracetam	TW
8655M	Tablet 500 mg	60	5	..	86.49	35.40	a	APO-Levetiracetam	TX
NP							a	Chem mart Levetiracetam	CH
							a	Kepcet	GM
							a	Keppra	UC
							a	Kevtam	AF
							a	Levecetam 500	RZ
							a	Levetiracetam generichealth	GQ
							a	Levetiracetam SZ	SZ
							a	Levitaccord	RA
							a	Levitam 500	QA
							a	Terry White	TW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Chemists Levetiracetam	
8656N *NP*	Tablet 1 g	60	5	..	139.83	35.40	a	APO-Levetiracetam	TX
							a	Chem mart Levetiracetam	CH
							a	Kepcet	GM
							a	Keppra	UC
							a	Kevtam	AF
							a	Levecetam 1000	RZ
							a	Levetiracetam generichealth	GQ
							a	Levetiracetam SZ	SZ
							a	Levitaccord	RA
							a	Levitam 1000	QA
							a	Terry White Chemists Levetiracetam	TW

LEVETIRACETAM

Authority required (STREAMLINED)

3291

Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9169N *NP*	Oral solution 100 mg per mL, 300 mL	‡1	5	..	111.42	35.40	Keppra	UC

SULTHIAME

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2099L *NP*	Tablet 50 mg	200	2	..	82.47	35.40	Ospolot	PL
2100M *NP*	Tablet 200 mg	200	2	..	205.99	35.40	Ospolot	PL

TOPIRAMATE

Authority required (STREAMLINED)

2797

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs.

Authority required (STREAMLINED)

2799

Prophylaxis of migraine in a patient who has experienced an average of 3 or more migraines per month over a period of at least 6 months, and who:
(a) has a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
(b) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker;
AND
(c) has a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
(d) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8163P	Tablet 25 mg	60	5	..	36.47	35.40	a	APO-Topiramate	TX
NP							a	Epiramax 25	QA
							a	RBX Topiramate	RA
							a	Tamate	AF
							a	Topamax	JC
							a	Topiramate-GA	GM
							a	Topiramate Sandoz	SZ
8164Q	Tablet 50 mg	60	5	..	53.81	35.40	a	APO-Topiramate	TX
NP							a	Epiramax 50	QA
							a	RBX Topiramate	RA
							a	Tamate	AF
							a	Topamax	JC
							a	Topiramate-GA	GM
							a	Topiramate Sandoz	SZ

TOPIRAMATE

Authority required (STREAMLINED)

2797

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8165R	Tablet 100 mg	60	5	..	80.64	35.40	a	APO-Topiramate	TX
NP							a	Epiramax 100	QA
							a	RBX Topiramate	RA
							a	Tamate	AF
							a	Topamax	JC
							a	Topiramate-GA	GM
							a	Topiramate Sandoz	SZ
8166T	Tablet 200 mg	60	5	..	131.09	35.40	a	APO-Topiramate	TX
NP							a	Epiramax 200	QA
							a	RBX Topiramate	RA
							a	Tamate	AF
							a	Topamax	JC
							a	Topiramate-GA	GM
							a	Topiramate Sandoz	SZ

TOPIRAMATE

Authority required (STREAMLINED)

2798

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8371N	Capsule 15 mg	60	5	..	28.28	29.37		Topamax Sprinkle	JC

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
NP								
8372P	Capsule 25 mg	60	5	..	35.98	35.40	Topamax Sprinkle	JC
NP								
8520K	Capsule 50 mg	60	5	..	53.76	35.40	Topamax Sprinkle	JC
NP								

ZONISAMIDE

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9388D	Capsule 25 mg	56	5	..	22.80	23.89	Zonegran	SA
NP								
9389E	Capsule 50 mg	56	5	..	33.72	34.81	Zonegran	SA
NP								
9390F	Capsule 100 mg	112	5	..	*93.46	35.40	Zonegran	SA
NP								

Anti-Parkinson drugs

Anticholinergic agents

Tertiary amines

BENZHEXOL HYDROCHLORIDE

1109J	Tablet 2 mg	200	2	..	15.32	16.41	Artane	QA
NP								
1110K	Tablet 5 mg	200	1	..	22.01	23.10	Artane	QA
NP								

BIPERIDEN HYDROCHLORIDE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2544X	Tablet 2 mg	200	2	..	*20.88	21.97	Akineton	LM
NP								

Ethers of tropine or tropine derivatives

BENZTROPINE MESYLATE

2362H	Tablet 2 mg	60	2	..	12.76	13.85	Benztrop	PL
NP								
3038X	Injection 2 mg in 2 mL	5	..	..	103.59	35.40	Cogentin	FK
NP								

Dopaminergic agents

Dopa and dopa derivatives

LEVODOPA with BENSERAZIDE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2225D	Capsule 100 mg-25 mg	100	5	..	38.92	35.40	Madopar 125	RO
NP								
2226E	Capsule 200 mg-50 mg	100	5	..	50.01	35.40	Madopar	RO
NP								
2227F	Capsule 50 mg-12.5 mg	100	5	..	23.00	24.09	Madopar 62.5	RO
NP								
2228G	Tablet 200 mg-50 mg	100	5	..	50.01	35.40	Madopar	RO

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP									
2229H	Tablet 100 mg-25 mg	100	5	..	38.92	35.40		Madopar 125	RO
NP									
2231K	Capsule 100 mg-25 mg (sustained release)	100	5	..	42.00	35.40		Madopar HBS	RO
NP									
8218M	Dispersible tablet 50 mg-12.5 mg	100	5	..	23.00	24.09		Madopar Rapid 62.5	RO
NP									
8219N	Dispersible tablet 100 mg-25 mg	100	5	..	38.92	35.40		Madopar Rapid 125	RO
NP									

LEVODOPA with CARBIDOPA

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1242J	Tablet 100 mg-25 mg	100	5	..	38.29	35.40	a	Kinson	AF
NP									
				[B]5.19	43.48	35.40	a	Sinemet 100/25	MK
1245M	Tablet 250 mg-25 mg	100	5	..	45.09	35.40	a	Levo/Carbidopa Sandoz	SZ
NP									
				[B]2.92	48.01	35.40	a	Sinemet	MK

LEVODOPA with CARBIDOPA

Authority required (STREAMLINED)

1257

Parkinson's disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1255C	Tablet 200 mg-50 mg (modified release)	100	5	..	67.87	35.40		Sinemet CR	MK
NP									

LEVODOPA with CARBIDOPA

Authority required

Maintenance therapy following treatment which was commenced in a hospital-based movement disorder clinic, of a patient with advanced Parkinson disease with severe disabling motor fluctuations not adequately controlled by oral therapy.

Note

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8970D	Intestinal gel 20 mg-5 mg per mL, 100 mL	56	5	..	*11682.34	35.40		Duodopa	AB
NP									

LEVODOPA with CARBIDOPA and ENTACAPONE

Authority required (STREAMLINED)

3305

Parkinson disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect;

3306

Parkinson disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8797B *NP*	Tablet 50 mg-12.5 mg-200 mg	200	4	..	*311.88	35.40		Stalevo 50/12.5/200mg	NV
8798C *NP*	Tablet 100 mg-25 mg-200 mg	200	4	..	*341.92	35.40		Stalevo 100/25/200mg	NV
8799D *NP*	Tablet 150 mg-37.5 mg-200 mg	200	4	..	*371.96	35.40		Stalevo 150/37.5/200mg	NV
9292C *NP*	Tablet 200 mg-50 mg-200 mg	200	4	..	*399.62	35.40		Stalevo 200/50/200mg	NV
9344T *NP*	Tablet 75 mg-18.75 mg-200 mg	200	4	..	*325.12	35.40		Stalevo 75/18.75/200mg	NV
9345W *NP*	Tablet 125 mg-31.25 mg-200 mg	200	4	..	*353.96	35.40		Stalevo 125/31.25/200mg	NV

Adamantane derivatives

AMANTADINE HYDROCHLORIDE

Restricted benefit

Parkinson's disease which is not drug induced.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3016R *NP*	Capsule 100 mg	100	5	..	44.30	35.40		Symmetrel 100	NV

Dopamine agonists

BROMOCRIPTINE MESYLATE

Restricted benefit

Acromegaly;

Parkinson's disease;

Pathological hyperprolactinaemia where surgery is not indicated;

Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;

Pathological hyperprolactinaemia where radiotherapy is not indicated;

Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.

Note

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

1443Y	Tablet 2.5 mg (base)	60	5	..	31.42	32.51	[a]	Kripton 2.5	AF
				..	*31.42	32.51	[a]	Parlodel	NV
1445C	Capsule 10 mg (base)	100	5	..	148.46	35.40		Kripton 10	AF
1446D	Capsule 5 mg (base)	60	5	..	48.28	35.40		Kripton 5	AF

CABERGOLINE

Restricted benefit

Parkinson's disease.

Note

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8393R *NP*	Tablet 1 mg	30	5	..	59.78	35.40	[a]	Bergoline 1	QA
							[a]	Cabaser	PF
							[a]	Cobasol	GM
8394T *NP*	Tablet 2 mg	30	5	..	77.94	35.40	[a]	Bergoline 2	QA
							[a]	Cabaser	PF

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
						[a]	Cobasol	GM

PERGOLIDE MESYLATE

Restricted benefit

Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.

Note

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2808T *NP*	Tablet 50 micrograms (base)	100	..	..	52.93	35.40	Permax	AS
2809W *NP*	Tablet 250 micrograms (base)	100	5	..	66.18	35.40	Permax	AS
2810X *NP*	Tablet 1 mg (base)	100	5	..	241.69	35.40	Permax	AS

PRAMIPEXOLE HYDROCHLORIDE

Caution

Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Note

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Parkinson disease.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9151P *NP*	Tablet 125 micrograms	30	..	..	11.74	12.83	Sifrol	BY
9152Q *NP*	Tablet 250 micrograms	100	5	..	41.27	35.40	Sifrol	BY
9153R *NP*	Tablet 1 mg	100	5	..	152.14	35.40	Sifrol	BY

PRAMIPEXOLE HYDROCHLORIDE

Caution

Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Note

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Treatment of severe primary Restless Legs Syndrome in a patient who manifests all 4 diagnostic criteria below and whose baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score is greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:
(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and
(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and
(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

Pramipexole is not PBS-subsidised for Restless Legs Syndrome secondary to other causes.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9393J *NP*	Tablet 125 micrograms	30	2	..	11.74	12.83		Sifrol	BY
9394K *NP*	Tablet 250 micrograms	100	2	..	41.27	35.40		Sifrol	BY
	PRAMIPEXOLE HYDROCHLORIDE **Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.								
	Note Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.								
	Restricted benefit Parkinson disease.								
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
	Note No applications for increased maximum quantities and/or repeats will be approved for extended release pramipexole formulations.								
3418X *NP*	Tablet 0.375 mg (extended release)	30	5	..	22.39	23.48		Sifrol ER	BY
3419Y *NP*	Tablet 0.75 mg (extended release)	30	5	..	37.84	35.40		Sifrol ER	BY
3420B *NP*	Tablet 1.5 mg (extended release)	30	5	..	66.51	35.40		Sifrol ER	BY
3421C *NP*	Tablet 3 mg (extended release)	30	5	..	137.56	35.40		Sifrol ER	BY
3422D *NP*	Tablet 4.5 mg (extended release)	30	5	..	203.13	35.40		Sifrol ER	BY
5143Q *NP*	Tablet 2.25 mg (extended release)	30	5	..	96.57	35.40		Sifrol ER	BY
5145T *NP*	Tablet 3.75 mg (extended release)	30	5	..	167.61	35.40		Sifrol ER	BY

Monoamine oxidase type B inhibitors

SELEGILINE HYDROCHLORIDE

Restricted benefit

Late stage Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1973W *NP*	Tablet 5 mg	100	5	..	52.96	35.40	[a]	Eldepryl	AS
							[a]	Selgene	AF

Other dopaminergic agents

ENTACAPONE

Authority required (STREAMLINED)

2067

Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
8367J *NP*	Tablet 200 mg	200	4	..	*281.82	35.40	Comtan	NV

Psycholeptics

Antipsychotics

Phenothiazine with aliphatic side-chain

CHLORPROMAZINE HYDROCHLORIDE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1195X *NP*	Injection 50 mg in 2 mL	10	..	..	20.48	21.57	Largactil	SW
1196Y *NP*	Tablet 10 mg	100	5	..	10.49	11.58	Largactil	SW
1197B *NP*	Tablet 25 mg	100	5	..	11.09	12.18	Largactil	SW
1199D *NP*	Tablet 100 mg	100	5	..	17.44	18.53	Largactil	SW
1201F *NP*	Mixture 25 mg per 5 mL, 100 mL	‡1	5	..	12.57	13.66	Largactil	SW

Phenothiazine with piperazine structure

FLUPHENAZINE DECANOATE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1001Q *NP*	Injection 50 mg in 2 mL	5	..	..	37.65	35.40	Modecate	BQ
1046C *NP*	Injection 12.5 mg in 0.5 mL	5	..	..	19.22	20.31	Modecate	BQ
3098C *NP*	Injection 25 mg in 1 mL	5	..	..	26.38	27.47	Modecate	BQ

TRIFLUOPERAZINE HYDROCHLORIDE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2185B *NP*	Tablet 1 mg (base)	100	5	..	13.31	14.40	Stelazine	GH
2186C *NP*	Tablet 5 mg (base)	100	5	..	13.86	14.95	Stelazine	GH
2386N *NP*	Tablet 2 mg (base)	100	5	..	13.48	14.57	Stelazine	GH

Phenothiazines with piperidine structure

PERICYAZINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3052P *NP*	Tablet 2.5 mg	100	5	..	10.41	11.50	Neulactil	SW
3053Q *NP*	Tablet 10 mg	100	5	..	14.46	15.55	Neulactil	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Butyrophenone derivatives							
	HALOPERIDOL							
	Note							
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2761H *NP*	Tablet 500 micrograms	100	5	..	10.56	11.65	Serenace	QA
2763K *NP*	Oral liquid 2 mg per mL, 100 mL	‡1	5	..	20.45	21.54	Serenace	QA
2767P *NP*	Tablet 1.5 mg	100	5	..	10.91	12.00	Serenace	QA
2768Q *NP*	Injection 5 mg in 1 mL	10	..	..	22.28	23.37	Serenace	QA
2770T *NP*	Tablet 5 mg	50	5	..	10.68	11.77	Serenace	QA
	HALOPERIDOL DECANOATE							
	Note							
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2765M *NP*	I.M. injection equivalent to 50 mg haloperidol in 1 mL	5	..	..	26.67	27.76	Haldol decanoate	JC
2766N *NP*	I.M. injection equivalent to 150 mg haloperidol in 3 mL	5	..	..	46.23	35.40	Haldol decanoate	JC
	Indole derivatives							
	ZIPRASIDONE HYDROCHLORIDE							
	Authority required (STREAMLINED)							
	1589 Schizophrenia.							
	Authority required (STREAMLINED)							
	3084 Monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder.							
	Note							
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9070J *NP*	Capsule 20 mg (base)	60	5	..	90.61	35.40	Zeldox	PF
9071K *NP*	Capsule 40 mg (base)	60	5	..	175.11	35.40	Zeldox	PF
9072L *NP*	Capsule 60 mg (base)	60	5	..	253.63	35.40	Zeldox	PF
9073M *NP*	Capsule 80 mg (base)	60	5	..	330.43	35.40	Zeldox	PF
	Thioxanthene derivatives							
	FLUPENTHIXOL DECANOATE							
	Note							
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2255Q *NP*	Oily I.M. injection 20 mg in 1 mL	5	..	..	20.51	21.60	Fluanxol Depot	LU
2257T *NP*	Oily I.M. injection 100 mg in 1 mL	5	..	..	48.27	35.40	Fluanxol Concentrated Depot	LU

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ZUCLOPENTHIXOL DECANOATE								
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8097E *NP*	Oily I.M. injection 200 mg in 1 mL	5	..	..	27.24	28.33		Clopixol Depot	LU

Diazepines, oxazepines, thiazepines and oxepines

ASENAPINE

Authority required (STREAMLINED)

1589

Schizophrenia;

3935

Treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder;

3936

Maintenance treatment, as monotherapy, of bipolar I disorder.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5140M *NP*	Sublingual wafer 5 mg (as maleate)	60	5	..	157.07	35.40		Saphris	LU
5141N *NP*	Sublingual wafer 10 mg (as maleate)	60	5	..	252.72	35.40		Saphris	LU

OLANZAPINE

Authority required (STREAMLINED)

1589

Schizophrenia;

2044

Maintenance treatment of bipolar I disorder.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

1024X *NP*	Tablet 2.5 mg (as benzoate)	28	5	..	46.73	35.40	[a]	Olanzapine genericehealth 2.5	GQ
							[a]	Olanzapine-Synthon	ZT
8170B *NP*	Tablet 2.5 mg	28	5	..	46.73	35.40	[a]	APO-Olanzapine	TX
							[a]	Chem mart Olanzapine	CH
							[a]	Lanzek	EL
							[a]	Olanzapine-DRLA	RZ
							[a]	Olanzapine-GA	GM
							[a]	Olanzapine-PS	FZ
							[a]	Olanzapine RBX	RA
							[a]	Olanzapine Sandoz	SZ
							[a]	Ozin 2.5	DO
							[a]	Terry White Chemists Olanzapine	TW
							[a]	Zylap 2.5	QA

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Zypine	AF
							[a]	Zyprexa	LY

OLANZAPINE

Authority required (STREAMLINED)

1589

Schizophrenia;

2044

Maintenance treatment of bipolar I disorder.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

1037N *NP*	Tablet 5 mg (as benzoate)	28	5	..	84.41	35.40	[a]	Olanzapine generichealth 5	GQ
							[a]	Olanzapine-Synthon	ZT
8185T *NP*	Tablet 5 mg	28	5	..	84.41	35.40	[a]	APO-Olanzapine	TX
							[a]	Chem mart Olanzapine	CH
							[a]	Lanzek	EL
							[a]	Olanzapine-DRLA	RZ
							[a]	Olanzapine-GA	GM
							[a]	Olanzapine-PS	FZ
							[a]	Olanzapine RBX	RA
							[a]	Olanzapine Sandoz	SZ
							[a]	Ozin 5	DO
							[a]	Terry White Chemists Olanzapine	TW
							[a]	Zylap 5	QA
							[a]	Zypine	AF
							[a]	Zyprexa	LY

OLANZAPINE

Authority required (STREAMLINED)

1589

Schizophrenia;

2044

Maintenance treatment of bipolar I disorder.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

1041T *NP*	Tablet 7.5 mg (as benzoate)	28	5	..	124.60	35.40	[a]	Olanzapine generichealth 7.5	GQ
							[a]	Olanzapine-Synthon	ZT

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8186W *NP*	Tablet 7.5 mg	28	5	..	124.60	35.40	a	APO-Olanzapine	TX
							a	Chem mart Olanzapine	CH
							a	Lanzek	EL
							a	Olanzapine-DRLA	RZ
							a	Olanzapine-GA	GM
							a	Olanzapine-PS	FZ
							a	Olanzapine RBX	RA
							a	Olanzapine Sandoz	SZ
							a	Ozin 7.5	DO
							a	Terry White Chemists Olanzapine	TW
							a	Zylap 7.5	QA
							a	Zypine	AF
							a	Zyprexa	LY

OLANZAPINE

Authority required (STREAMLINED)

1589

Schizophrenia;

2044

Maintenance treatment of bipolar I disorder.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

1042W *NP*	Tablet 10 mg (as benzoate)	28	5	..	164.00	35.40	a	Olanzapine generichealth 10	GQ
							a	Olanzapine-Synthon	ZT
8187X *NP*	Tablet 10 mg	28	5	..	164.00	35.40	a	APO-Olanzapine	TX
							a	Chem mart Olanzapine	CH
							a	Lanzek	EL
							a	Olanzapine-DRLA	RZ
							a	Olanzapine-GA	GM
							a	Olanzapine-PS	FZ
							a	Olanzapine RBX	RA
							a	Olanzapine Sandoz	SZ
							a	Ozin 10	DO
							a	Terry White Chemists Olanzapine	TW
							a	Zylap 10	QA
							a	Zypine	AF
							a	Zyprexa	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	OLANZAPINE **Authority required (STREAMLINED)** ***1589*** Schizophrenia; ***2044*** Maintenance treatment of bipolar I disorder. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.								
3381Y *NP*	Tablet 5 mg (orally disintegrating)	28	5	..	84.41	35.40	a	APO-Olanzapine ODT	TX
							a	Chem mart Olanzapine ODT	CH
							a	Olanzapine-GA ODT	GM
							a	Olanzapine ODT-DRLA	RZ
							a	Olanzapine ODT generichealth 5	GQ
							a	Olanzapine Sandoz ODT 5	SZ
							a	PS Olanzapine ODT	FZ
							a	Terry White Chemists Olanzapine ODT	TW
							a	Zylap ODT 5	QA
8433W *NP*	Wafer 5 mg	28	5	..	84.41	35.40	a	Lanzek Zydis	EL
							a	Zypine ODT	AF
							a	Zyprexa Zydis	LY
	OLANZAPINE **Authority required (STREAMLINED)** ***1589*** Schizophrenia; ***2044*** Maintenance treatment of bipolar I disorder. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. **Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.								
3382B *NP*	Tablet 10 mg (orally disintegrating)	28	5	..	164.00	35.40	a	APO-Olanzapine ODT	TX
							a	Chem mart Olanzapine ODT	CH
							a	Olanzapine-GA ODT	GM
							a	Olanzapine ODT-DRLA	RZ
							a	Olanzapine ODT generichealth 10	GQ
							a	Olanzapine Sandoz ODT 10	SZ
							a	PS Olanzapine ODT	FZ

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Terry White Chemists Olanzapine ODT	TW
							[a]	Zylap ODT 10	QA
8434X *NP*	Wafer 10 mg	28	5	..	164.00	35.40	[a]	Lanzek Zydis	EL
							[a]	Zypine ODT	AF
							[a]	Zyprexa Zydis	LY

OLANZAPINE
Authority required (STREAMLINED)
1589
Schizophrenia;

2044
Maintenance treatment of bipolar I disorder.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note
Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

3384D *NP*	Tablet 15 mg (orally disintegrating)	28	5	..	239.29	35.40	[a]	APO-Olanzapine ODT	TX
							[a]	Chem mart Olanzapine ODT	CH
							[a]	Terry White Chemists Olanzapine ODT	TW
8952E *NP*	Wafer 15 mg	28	5	..	239.29	35.40	[a]	Zyprexa Zydis	LY

OLANZAPINE
Authority required (STREAMLINED)
1589
Schizophrenia;

2044
Maintenance treatment of bipolar I disorder.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note
Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

3385E *NP*	Tablet 20 mg (orally disintegrating)	28	5	..	310.90	35.40	[a]	APO-Olanzapine ODT	TX
							[a]	Chem mart Olanzapine ODT	CH
							[a]	Terry White Chemists Olanzapine ODT	TW
8953F *NP*	Wafer 20 mg	28	5	..	310.90	35.40	[a]	Zyprexa Zydis	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	OLANZAPINE								
	Authority required (STREAMLINED)								
	1589								
	Schizophrenia.								
	Caution								
	Monitor for post-injection syndrome for at least three hours after each injection.								
	Note								
	Shared Care Model:								
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
	Note								
	Special Pricing Arrangements apply.								
9294E *NP*	Powder for injection 210 mg (as pamoate monohydrate) with diluent	2	5	..	*499.78	35.40		Zyprexa Relprevv	LY
9295F *NP*	Powder for injection 300 mg (as pamoate monohydrate) with diluent	2	5	..	*809.26	35.40		Zyprexa Relprevv	LY
9303P *NP*	Powder for injection 405 mg (as pamoate monohydrate) with diluent	1	5	..	499.78	35.40		Zyprexa Relprevv	LY
	QUETIAPINE								
	Authority required (STREAMLINED)								
	1589								
	Schizophrenia;								
	2765								
	Monotherapy, for up to 6 months, of an episode of acute mania associated with bipolar I disorder;								
	2044								
	Maintenance treatment of bipolar I disorder.								
	Note								
	Shared Care Model:								
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
5458G *NP*	Tablet (modified release) 150 mg (as fumarate)	60	5	..	118.18	35.40		Seroquel XR	AP
8456C *NP*	Tablet 25 mg (as fumarate)	60	5	..	46.82	35.40	[a]	APO-Quetiapine	TX
							[a]	Chem mart Quetiapine	CH
							[a]	Delucon 25	DO
							[a]	Quetiaccord	WQ
							[a]	Quetiapine Actavis 25	TA
							[a]	Quetiapine-DRLA	RZ
							[a]	Quetiapine GH 25	GQ
							[a]	Quetiapine Pfizer	FZ
							[a]	Quetiapine RBX	RA
							[a]	Quetiapine Sandoz	SZ
							[a]	Quipine	GM
							[a]	Sequase	PM
							[a]	Seronia 25	QA
							[a]	Seroquel	AP
							[a]	Syquet	AF
							[a]	Terry White Chemists Quetiapine	TW
8457D *NP*	Tablet 100 mg (as fumarate)	90	5	..	118.18	35.40	[a]	APO-Quetiapine	TX
							[a]	Chem mart Quetiapine	CH
							[a]	Delucon 100	DO

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Quetiaccord	WQ
							[a]	Quetiapine Actavis 100	TA
							[a]	Quetiapine-DRLA	RZ
							[a]	Quetiapine GH 100	GQ
							[a]	Quetiapine Pfizer	FZ
							[a]	Quetiapine RBX	RA
							[a]	Quetiapine Sandoz	SZ
							[a]	Quipine	GM
							[a]	Sequase	PM
							[a]	Seronia 100	QA
							[a]	Seroquel	AP
							[a]	Syquet	AF
							[a]	Terry White Chemists Quetiapine	TW
8458E *NP*	Tablet 200 mg (as fumarate)	60	5	..	158.69	35.40	[a]	APO-Quetiapine	TX
							[a]	Chem mart Quetiapine	CH
							[a]	Delucon 200	DO
							[a]	Quetiaccord	WQ
							[a]	Quetiapine Actavis 200	TA
							[a]	Quetiapine-DRLA	RZ
							[a]	Quetiapine GH 200	GQ
							[a]	Quetiapine Pfizer	FZ
							[a]	Quetiapine RBX	RA
							[a]	Quetiapine Sandoz	SZ
							[a]	Quipine	GM
							[a]	Sequase	PM
							[a]	Seronia 200	QA
							[a]	Seroquel	AP
							[a]	Syquet	AF
							[a]	Terry White Chemists Quetiapine	TW
8580N *NP*	Tablet 300 mg (as fumarate)	60	5	..	227.54	35.40	[a]	APO-Quetiapine	TX
							[a]	Chem mart Quetiapine	CH
							[a]	Delucon 300	DO
							[a]	Quetiaccord	WQ
							[a]	Quetiapine Actavis 300	TA
							[a]	Quetiapine-DRLA	RZ
							[a]	Quetiapine GH 300	GQ
							[a]	Quetiapine Pfizer	FZ
							[a]	Quetiapine RBX	RA
							[a]	Quetiapine Sandoz	SZ
							[a]	Quipine	GM
							[a]	Sequase	PM
							[a]	Seronia 300	QA
							[a]	Seroquel	AP
							[a]	Syquet	AF
							[a]	Terry White	TW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Chemists Quetiapine	
9202H *NP*	Tablet (modified release) 50 mg (as fumarate)	60	5	..	85.40	35.40		Seroquel XR	AP
9203J *NP*	Tablet (modified release) 200 mg (as fumarate)	60	5	..	158.69	35.40		Seroquel XR	AP
9204K *NP*	Tablet (modified release) 300 mg (as fumarate)	60	5	..	227.54	35.40		Seroquel XR	AP
9205L *NP*	Tablet (modified release) 400 mg (as fumarate)	60	5	..	301.28	35.40		Seroquel XR	AP

Benzamides

AMISULPRIDE

Authority required (STREAMLINED)

1589

Schizophrenia.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8594H *NP*	Tablet 100 mg	30	5	..	32.63	33.72	[a]	Amisulpride 100 Winthrop	WA
							[a]	Amisulpride Sandoz	SZ
							[a]	APO-Amisulpride	TX
							[a]	Solian 100	SW
							[a]	Sulprix	AF
8595J *NP*	Tablet 200 mg	60	5	..	114.44	35.40	[a]	Amisulpride 200 Winthrop	WA
							[a]	Amisulpride Sandoz	SZ
							[a]	APO-Amisulpride	TX
							[a]	Solian 200	SW
							[a]	Sulprix	AF
8596K *NP*	Tablet 400 mg	60	5	..	202.29	35.40	[a]	Amipride 400	QA
							[a]	Amisulpride 400 Winthrop	WA
							[a]	Amisulpride Sandoz	SZ
							[a]	APO-Amisulpride	TX
							[a]	Solian 400	SW
							[a]	Sulprix	AF
8736T *NP*	Oral solution 100 mg per mL, 60 mL	2	5	..	*148.74	35.40		Solian Solution	SW

Lithium

LITHIUM CARBONATE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3059B *NP*	Tablet 250 mg	200	2	..	16.89	17.98	Lithicarb	AS
8290H *NP*	Tablet 450 mg (slow release)	200	2	..	*34.30	35.39	Quilonum SR	GK

Other antipsychotics

ARIPIPRAZOLE

Authority required (STREAMLINED)

1589

Schizophrenia.

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8717T *NP*	Tablet 10 mg	30	5	..	152.25	35.40	Abilify	BQ
8718W *NP*	Tablet 15 mg	30	5	..	212.56	35.40	Abilify	BQ
8719X *NP*	Tablet 20 mg	30	5	..	253.43	35.40	Abilify	BQ
8720Y *NP*	Tablet 30 mg	30	5	..	303.49	35.40	Abilify	BQ
	PALIPERIDONE **Authority required (STREAMLINED)** ***1589*** Schizophrenia.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
	Note Special Pricing Arrangements apply to 3 mg and 6 mg strengths.							
9140C *NP*	Tablet 3 mg (prolonged release)	28	5	..	161.07	35.40	Invega	JC
9141D *NP*	Tablet 6 mg (prolonged release)	28	5	..	169.68	35.40	Invega	JC
	PALIPERIDONE **Authority required (STREAMLINED)** ***1589*** Schizophrenia.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5100K *NP*	I.M. injection (modified release) 25 mg (as palmitate) in pre-filled syringe	1	5	..	149.63	35.40	Invega Sustenna	JC
5102M *NP*	I.M. injection (modified release) 50 mg (as palmitate) in pre-filled syringe	1	5	..	284.80	35.40	Invega Sustenna	JC
5103N *NP*	I.M. injection (modified release) 75 mg (as palmitate) in pre-filled syringe	1	5	..	363.14	35.40	Invega Sustenna	JC
5107T *NP*	I.M. injection (modified release) 100 mg (as palmitate) in pre-filled syringe	1	5	..	440.69	35.40	Invega Sustenna	JC
5109X *NP*	I.M. injection (modified release) 150 mg (as palmitate) in pre-filled syringe	1	5	..	440.69	35.40	Invega Sustenna	JC
9142E *NP*	Tablet 9 mg (prolonged release)	28	5	..	226.01	35.40	Invega	JC
	RISPERIDONE **Authority required (STREAMLINED)** ***2061*** Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful.							
	Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.							
	Authority required (STREAMLINED) ***3083*** Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age. Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful. The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8787L *NP*	Tablet 0.5 mg	60	2	..	26.59	27.68	a	Ozidal	RA
							a	Resdone 0.5	CR
							a	Rispa	QA
							a	Risperidone Actavis 0.5	TA
							a	Risperidone-DRLA	RZ
							a	Risperidone-GA	GM
							a	Risperidone Pfizer	FZ
							a	Risperidone Sandoz	SZ
							a	Rixadone	AF
				..	*26.61	27.70	a	APO-Risperidone	TX
							a	Risperdal	JC
8788M *NP*	Tablet 0.5 mg (orally disintegrating)	56	2	..	*29.00	30.09		Risperdal Quicklet	JC
8789N *NP*	Tablet 1 mg	60	2	..	44.77	35.40	a	APO-Risperidone	TX
							a	Ozidal	RA
							a	Resdone 1	CR
							a	Rispa	QA
							a	Risperdal	JC
							a	Risperidone Actavis 1	TA
							a	Risperidone-DRLA	RZ
							a	Risperidone-GA	GM
							a	Risperidone generichealth	GQ
							a	Risperidone Pfizer	FZ
							a	Risperidone Sandoz	SZ
							a	Rixadone	AF
8790P *NP*	Tablet 1 mg (orally disintegrating)	56	2	..	*50.20	35.40		Risperdal Quicklet	JC
9293D *NP*	Oral solution 1 mg per mL, 100 mL	‡1	2	..	118.03	35.40		Risperdal	JC
	RISPERIDONE **Authority required (STREAMLINED)** ***1589*** Schizophrenia. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8869T	Tablet 0.5 mg	60	5	..	26.59	27.68	a	Ozidal	RA

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP									
							[a]	Resdone 0.5	CR
							[a]	Rispa	QA
							[a]	Risperidone Actavis 0.5	TA
							[a]	Risperidone-DRLA	RZ
							[a]	Risperidone-GA	GM
							[a]	Risperidone Pfizer	FZ
							[a]	Risperidone Sandoz	SZ
							[a]	Rixadone	AF
				..	*26.61	27.70	[a]	APO-Risperidone	TX
							[a]	Risperdal	JC
8870W	Tablet 0.5 mg (orally disintegrating)	56	5	..	*29.00	30.09		Risperdal Quicklet	JC
NP									

RISPERIDONE

Authority required (STREAMLINED)

1589

Schizophrenia.

Authority required (STREAMLINED)

2272

Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3169T	Tablet 1 mg	60	5	..	44.77	35.40	[a]	APO-Risperidone	TX
NP									
							[a]	Ozidal	RA
							[a]	Resdone 1	CR
							[a]	Rispa	QA
							[a]	Risperdal	JC
							[a]	Risperidone Actavis 1	TA
							[a]	Risperidone-DRLA	RZ
							[a]	Risperidone-GA	GM
							[a]	Risperidone generichealth	GQ
							[a]	Risperidone Pfizer	FZ
							[a]	Risperidone Sandoz	SZ
							[a]	Rixadone	AF
3170W	Tablet 2 mg	60	5	..	91.57	35.40	[a]	APO-Risperidone	TX
NP									
							[a]	Ozidal	RA
							[a]	Resdone 2	CR
							[a]	Rispa	QA
							[a]	Risperdal	JC
							[a]	Risperidone Actavis 2	TA
							[a]	Risperidone-DRLA	RZ
							[a]	Risperidone-GA	GM
							[a]	Risperidone generichealth	GQ
							[a]	Risperidone Pfizer	FZ
							[a]	Risperidone Sandoz	SZ

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Rixadone	AF
3171X *NP*	Tablet 3 mg	60	5	..	137.74	35.40	[a]	APO-Risperidone	TX
							[a]	Ozidal	RA
							[a]	Resdone 3	CR
							[a]	Rispa	QA
							[a]	Risperdal	JC
							[a]	Risperidone Actavis 3	TA
							[a]	Risperidone-DRLA	RZ
							[a]	Risperidone-GA	GM
							[a]	Risperidone generichealth	GQ
							[a]	Risperidone Pfizer	FZ
							[a]	Risperidone Sandoz	SZ
							[a]	Rixadone	AF
3172Y *NP*	Tablet 4 mg	60	5	..	183.69	35.40	[a]	APO-Risperidone	TX
							[a]	Ozidal	RA
							[a]	Resdone 4	CR
							[a]	Rispa	QA
							[a]	Risperdal	JC
							[a]	Risperidone Actavis 4	TA
							[a]	Risperidone-DRLA	RZ
							[a]	Risperidone-GA	GM
							[a]	Risperidone generichealth	GQ
							[a]	Risperidone Pfizer	FZ
							[a]	Risperidone Sandoz	SZ
							[a]	Rixadone	AF
8100H *NP*	Oral solution 1 mg per mL, 100 mL	‡1	5	..	118.03	35.40		Risperdal	JC
8792R *NP*	Tablet 1 mg (orally disintegrating)	56	5	..	*50.20	35.40		Risperdal Quicklet	JC
8794W *NP*	Tablet 2 mg (orally disintegrating)	56	5	..	*93.24	35.40		Risperdal Quicklet	JC
9075P *NP*	Tablet 3 mg (orally disintegrating)	56	5	..	*135.42	35.40		Risperdal Quicklet	JC
9076Q *NP*	Tablet 4 mg (orally disintegrating)	56	5	..	*178.32	35.40		Risperdal Quicklet	JC

RISPERIDONE

Authority required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9079W *NP*	Tablet 2 mg	60	2	..	91.57	35.40	[a]	APO-Risperidone	TX
							[a]	Ozidal	RA
							[a]	Resdone 2	CR
							[a]	Rispa	QA
							[a]	Risperdal	JC
							[a]	Risperidone Actavis 2	TA
							[a]	Risperidone-DRLA	RZ
							[a]	Risperidone-GA	GM
							[a]	Risperidone generichealth	GQ
							[a]	Risperidone Pfizer	FZ
							[a]	Risperidone Sandoz	SZ
							[a]	Rixadone	AF
9080X *NP*	Tablet 2 mg (orally disintegrating)	56	2	..	*93.24	35.40		Risperdal Quicklet	JC
	RISPERIDONE **Authority required (STREAMLINED)** ***1589*** Schizophrenia; ***3841*** Maintenance treatment, in combination with lithium or sodium valproate, of treatment refractory bipolar I disorder. **Note** **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8780D *NP*	Powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	*277.10	35.40		Risperdal Consta	JC
8781E *NP*	Powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	*353.44	35.40		Risperdal Consta	JC
8782F *NP*	Powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	*428.98	35.40		Risperdal Consta	JC

Anxiolytics

Benzodiazepine derivatives

	ALPRAZOLAM **Authority required** Panic disorder where other treatments have failed or are inappropriate.								
2130D *NP*	Tablet 250 micrograms	50	..	..	8.88	9.97	[a]	Alprax 0.25	QA
							[a]	Alprazolam Sandoz	SZ
							[a]	Kalma 0.25	AF
				[B]0.83	9.71	9.97	[a]	Xanax	PF
2131E *NP*	Tablet 500 micrograms	50	..	..	10.40	11.49	[a]	Alprax 0.5	QA
							[a]	Alprazolam Sandoz	SZ
							[a]	Kalma 0.5	AF
				[B]0.87	11.27	11.49	[a]	Xanax	PF
2132F *NP*	Tablet 1 mg	50	2	..	13.35	14.44	[a]	Alprax 1	QA
							[a]	Alprazolam Sandoz	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Chem mart Alprazolam	CH
							[a]	GenRx Alprazolam	GX
							[a]	Kalma 1	AF
							[a]	Ralozam	GM
							[a]	Terry White Chemists Alprazolam	TW
				[B]1.04	14.39	14.44	[a]	Xanax	PF
8118G *NP*	Tablet 2 mg	50	2	..	17.16	18.25	[a]	Alprax 2	QA
							[a]	Alprazolam Sandoz	SZ
							[a]	Chem mart Alprazolam	CH
							[a]	GenRx Alprazolam	GX
							[a]	Kalma 2	AF
							[a]	Ralozam	GM
							[a]	Terry White Chemists Alprazolam	TW
				[B]1.25	18.41	18.25	[a]	Xanax Tri-Score	PF

DIAZEPAM

Note

Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or

(ii) malignant neoplasia (late stage); or

(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or

(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.
Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

2558P *NP*	Injection 10 mg in 2 mL	5	..	..	12.29	13.38		Hospira Pty Limited	HH
3161J *NP*	Tablet 2 mg	50	..	..	7.72	8.81	[a]	Antenex 2	AF
							[a]	APO-Diazepam	TX
							[a]	Ranzepam	RA
							[a]	Valpam 2	QA
				[B]0.82	8.54	8.81	[a]	Valium	RO
3162K *NP*	Tablet 5 mg	50	..	..	7.85	8.94	[a]	Antenex 5	AF
							[a]	APO-Diazepam	TX
							[a]	Diazepam-GA	GM
							[a]	Ranzepam	RA
							[a]	Valpam 5	QA
				[B]0.85	8.70	8.94	[a]	Valium	RO

OXAZEPAM

Note

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

3132W *NP*	Tablet 15 mg	25	..	..	7.65	8.74	[a]	Alepam 15	AF
				[B]2.69	10.34	8.74	[a]	Serepax	QA

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
3133X	Tablet 30 mg	25	..	..	7.65	8.74	a	Alepam 30	AF
NP							a	APO-Oxazepam	TX
							a	Murelax	FM
				B2.69	10.34	8.74	a	Serepax	QA

OXAZEPAM
Authority required
Malignant neoplasia (late stage);

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

3134Y	Tablet 15 mg	50	5	..	*8.88	9.97	a	Alepam 15	AF
NP				B5.38	*14.26	9.97	a	Serepax	QA
3135B	Tablet 30 mg	50	5	..	*8.88	9.97	a	Alepam 30	AF
NP							a	APO-Oxazepam	TX
							a	Murelax	FM
				B5.38	*14.26	9.97	a	Serepax	QA

Other anxiolytics

CLOMIPRAMINE HYDROCHLORIDE
Restricted benefit
Cataplexy associated with narcolepsy;

Obsessive-compulsive disorder;

Phobic disorders in adults.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1561E	Tablet 25 mg	50	2	..	15.09	16.18	a	Chem mart Clomipramine	CH
NP							a	GenRx Clomipramine	GX
							a	Placil	AF
							a	Terry White Chemists Clomipramine	TW
				B3.06	18.15	16.18	a	Anafranil 25	NV

Hypnotics and sedatives
Benzodiazepine derivatives

NITRAZEPAM
Note
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.

2723H	Tablet 5 mg	25	..	..	7.82	8.91	a	Alodorm	AF
NP				B1.45	9.27	8.91	a	Mogadon	VT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	NITRAZEPAM								
	Authority required								
	Myoclonic epilepsy;								
	Malignant neoplasia (late stage);								
	For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;								
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.								
	Note								
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2732T *NP*	Tablet 5 mg	50	5	..	*9.22	10.31	a	Alodorm	AF
				B2.90	*12.12	10.31	a	Mogadon	VT
	TEMAZEPAM								
	Note								
	Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam below.								
2089Y *NP*	Tablet 10 mg	25	..	..	7.46	8.55	a	APO-Temazepam	TX
							a	Temaze	AF
							a	Temtabs	FM
				B1.21	8.67	8.55	a	Normison	QA
	TEMAZEPAM								
	Authority required								
	Malignant neoplasia (late stage);								
	For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;								
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.								
	Note								
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2088X *NP*	Tablet 10 mg	50	5	..	*8.50	9.59	a	APO-Temazepam	TX
							a	Temaze	AF
							a	Temtabs	FM
				B2.42	*10.92	9.59	a	Normison	QA

Psychoanaleptics

Antidepressants

Non-selective monoamine reuptake inhibitors

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	AMITRIPTYLINE HYDROCHLORIDE								
	Note								
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2417F *NP*	Tablet 10 mg	50	2	..	8.44	9.53		Endep 10	AF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
2418G *NP*	Tablet 25 mg	50	2	..	8.56	9.65		Endep 25	AF
2429W *NP*	Tablet 50 mg	50	2	..	8.89	9.98		Endep 50	AF
	CLOMIPRAMINE HYDROCHLORIDE **Restricted benefit** Cataplexy associated with narcolepsy; Obsessive-compulsive disorder; Phobic disorders in adults. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1561E *NP*	Tablet 25 mg	50	2	..	15.09	16.18	[a]	Chem mart Clomipramine	CH
							[a]	GenRx Clomipramine	GX
							[a]	Placil	AF
							[a]	Terry White Chemists Clomipramine	TW
				[B]3.06	18.15	16.18	[a]	Anafranil 25	NV
	DOTHIEPIN HYDROCHLORIDE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1357K *NP*	Capsule 25 mg	50	2	..	9.38	10.47		Dothep 25	AF
1358L *NP*	Tablet 75 mg	30	2	..	9.38	10.47		Dothep 75	AF
	DOXEPIN HYDROCHLORIDE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1011F *NP*	Capsule 10 mg (base)	50	2	..	8.97	10.06		Deptran 10	AF
				[B]1.87	10.84	10.06		Sinequan	PF
1012G *NP*	Tablet 50 mg (base)	50	2	..	9.71	10.80		Deptran 50	AF
1013H *NP*	Capsule 25 mg (base)	50	2	..	9.40	10.49		Deptran 25	AF
				[B]1.57	10.97	10.49		Sinequan	PF
	IMIPRAMINE HYDROCHLORIDE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2420J *NP*	Tablet 10 mg	50	2	..	8.54	9.63	[a]	Tolerade 10	PQ
				[B]2.79	11.33	9.63	[a]	Tofranil 10	LM
2421K *NP*	Tablet 25 mg	50	2	..	12.43	13.52	[a]	Tolerade 25	PQ
				[B]2.79	15.22	13.52	[a]	Tofranil 25	LM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	NORTRIPTYLINE HYDROCHLORIDE								
	Restricted benefit								
	Major depression where other antidepressant therapy has failed;								
	Major depression where other antidepressant therapy is contraindicated.								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2522R *NP*	Tablet 10 mg (base)	50	2	..	13.32	14.41		Allegron	AS
2523T *NP*	Tablet 25 mg (base)	50	2	..	15.10	16.19		Allegron	AS

Selective serotonin reuptake inhibitors

	CITALOPRAM HYDROBROMIDE								
	Restricted benefit								
	Major depressive disorders.								
8220P *NP*	Tablet 20 mg (base)	28	5	..	13.46	14.55	[a]	APO-Citalopram	TX
							[a]	Auro-Citalopram 20	DO
							[a]	Celapram	AF
							[a]	Celica	RA
							[a]	Chem mart Citalopram	CH
							[a]	Ciazil	GM
							[a]	Citalobell	BF
							[a]	Citalopram 20	CR
							[a]	Citalopram-GA	GN
							[a]	Citalopram generichealth	GQ
							[a]	Citalopram Pfizer	FZ
							[a]	Citalopram Sandoz	SZ
							[a]	GenRx Citalopram	GX
							[a]	Pharmacor Citalo 20	MI
							[a]	Talam	QA
							[a]	Terry White Chemists Citalopram	TW
				[B]2.00	15.46	14.55	[a]	Cipramil	LU
8702B *NP*	Tablet 10 mg (base)	28	5	..	11.05	12.14		Celapram	AF
8703C *NP*	Tablet 40 mg (base)	28	5	..	18.32	19.41	[a]	APO-Citalopram	TX
							[a]	Auro-Citalopram 40	DO
							[a]	Celapram	AF
							[a]	Citalopram Pfizer	FZ
							[a]	Citalopram Sandoz	SZ
							[a]	GenRx Citalopram	GX
	ESCITALOPRAM								
	Restricted benefit								
	Major depressive disorders.								
8700X *NP*	Tablet 10 mg (as oxalate)	28	5	..	21.04	22.13	[a]	APO-Escitalopram	TX
							[a]	Chem mart Escitalopram	CH
							[a]	Escicor 10	MI

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Escitalopram-DRLA	RZ
							[a]	Escitalopram GA	GN
							[a]	Escitalopram generichealth	GQ
							[a]	Esipram	GM
							[a]	Esitalo	SZ
							[a]	Lexam 10	QA
							[a]	LoxaLate	AF
							[a]	Pharmacor Escitalopram 10	CR
							[a]	Terry White Chemists Escitalopram	TW
				[B]4.70	25.74	22.13	[a]	Lexapro	LU
8701Y *NP*	Tablet 20 mg (as oxalate)	28	5	..	21.13	22.22	[a]	APO-Escitalopram	TX
							[a]	Chem mart Escitalopram	CH
							[a]	Escicor 20	MI
							[a]	Escitalopram-DRLA	RZ
							[a]	Escitalopram GA	GN
							[a]	Escitalopram generichealth	GQ
							[a]	Esipram	GM
							[a]	Esitalo	SZ
							[a]	Lexam 20	QA
							[a]	LoxaLate	AF
							[a]	Pharmacor Escitalopram 20	CR
							[a]	Terry White Chemists Escitalopram	TW
				[B]6.85	27.98	22.22	[a]	Lexapro	LU

ESCITALOPRAM

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:
(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or

(b) who has been assessed by a psychiatrist;

Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:
(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or

(b) who has been assessed by a psychiatrist;

Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 March 2008.

9432K *NP*	Tablet 10 mg (as oxalate)	28	5	..	21.04	22.13	[a]	Esipram	GM
				[B]4.70	25.74	22.13	[a]	Lexapro	LU
9433L *NP*	Tablet 20 mg (as oxalate)	28	5	..	21.13	22.22	[a]	Esipram	GM
				[B]6.85	27.98	22.22	[a]	Lexapro	LU

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ESCITALOPRAM								
	Restricted benefit								
	Major depressive disorders.								
	Restricted benefit								
	Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and: (a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or								
	(b) who has been assessed by a psychiatrist;								
	Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 November 2008.								
	Restricted benefit								
	Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and: (a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or								
	(b) who has been assessed by a psychiatrist;								
	Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 November 2008.								
8849R *NP*	Oral solution 10 mg (as oxalate) per mL, 28 mL	‡1	5	..	34.30	35.39		Lexapro	LU
	FLUOXETINE								
	Restricted benefit								
	Major depressive disorders;								
	Obsessive-compulsive disorder.								
1434L *NP*	Capsule 20 mg (as hydrochloride)	28	5	..	17.54	18.63	[a]	Auscap	QA
							[a]	Chem mart Fluoxetine	CH
							[a]	Fluoxetine 20	CR
							[a]	Fluoxetine-GA	GM
							[a]	Fluoxetine generichealth	GQ
							[a]	Fluoxetine-PS	FZ
							[a]	Fluoxetine RBX	RA
							[a]	Fluoxetine Sandoz	SZ
							[a]	GenRx Fluoxetine	GX
							[a]	Lovan	AL
							[a]	Terry White Chemists Fluoxetine	TW
							[a]	Zactin	AF
				[B]3.53	21.07	18.63	[a]	Prozac 20	LY
8270G *NP*	Tablet, dispersible, 20 mg (as hydrochloride)	28	5	..	17.54	18.63	[a]	Lovan 20 Tab	AL
							[a]	Zactin Tablet	AF
				[B]3.53	21.07	18.63	[a]	Prozac Tab	LY
	FLUVOXAMINE								
	Restricted benefit								
	Major depressive disorders;								
	Obsessive-compulsive disorder.								
8174F *NP*	Tablet containing fluvoxamine maleate 100 mg	30	5	..	22.84	23.93	[a]	APO-Fluvoxamine	TX
							[a]	Faverin 100	QA
							[a]	Fluvoxamine GA	GM
							[a]	Movox 100	AF

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Voxam	SZ
				[B]2.30	25.14	23.93	[a]	Luvox	AB
8512B *NP*	Tablet containing fluvoxamine maleate 50 mg	30	5	..	17.25	18.34	[a]	APO-Fluvoxamine	TX
							[a]	Faverin 50	QA
							[a]	Fluvoxamine GA	GM
							[a]	Movox 50	AL
							[a]	Voxam	SZ
				[B]2.30	19.55	18.34	[a]	Luvox	AB

PAROXETINE

Restricted benefit

Major depressive disorders;

Obsessive-compulsive disorder;

Panic disorder.

Note

Pharmaceutical benefits that have the form paroxetine tablet 20 mg (as hydrochloride) and pharmaceutical benefits that have the form paroxetine tablet 20 mg (as mesilate) are equivalent for the purposes of substitution.

2242B *NP*	Tablet 20 mg (as hydrochloride)	30	5	..	17.10	18.19	[a]	Chem mart Paroxetine	CH
							[a]	Extine 20	QA
							[a]	GenRx Paroxetine	GX
							[a]	Paroxetine 20	CR
							[a]	Paroxetine-GA	GN
							[a]	Paroxetine Sandoz	SZ
							[a]	Paxtine	AF
							[a]	Roxet 20	DO
							[a]	Terry White Chemists Paroxetine	TW
				[B]0.80	17.90	18.19	[a]	Aropax	GK
9197C *NP*	Tablet 20 mg (as mesilate)	30	5	..	17.10	18.19	[a]	Paroxetine generichealth	GQ
							[a]	Paroxetine Synthon	ZT
							[a]	Pharmacor Paroxo 20	MI

SERTRALINE

Restricted benefit

Major depressive disorders.

2236Q *NP*	Tablet 50 mg (as hydrochloride)	30	5	..	15.91	17.00	[a]	Auro-Sertraline 50	DO
							[a]	Chem mart Sertraline	CH
							[a]	Eleva 50	AF
							[a]	GenRx Sertraline	GX
							[a]	Sertra 50	QA
							[a]	Sertracor 50	MI
							[a]	Sertraline 50	CR
							[a]	Sertraline-DRLA	RZ
							[a]	Sertraline-GA	GM
							[a]	Sertraline generichealth	GQ
							[a]	Sertraline Pfizer	FZ
							[a]	Sertraline Sandoz	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Setrona	RA
							[a]	Terry White Chemists Sertraline	TW
							[a]	Xydep 50	GN
				[B]0.77	16.68	17.00	[a]	Zoloft	PF
2237R *NP*	Tablet 100 mg (as hydrochloride)	30	5	..	15.91	17.00	[a]	Auro-Sertraline 100	DO
							[a]	Chem mart Sertraline	CH
							[a]	Eleva 100	AF
							[a]	GenRx Sertraline	GX
							[a]	Sertra 100	QA
							[a]	Sertracor 100	MI
							[a]	Sertraline 100	CR
							[a]	Sertraline-DRLA	RZ
							[a]	Sertraline-GA	GM
							[a]	Sertraline generichealth	GQ
							[a]	Sertraline Pfizer	FZ
							[a]	Sertraline Sandoz	SZ
							[a]	Setrona	RA
							[a]	Terry White Chemists Sertraline	TW
							[a]	Xydep 100	GN
				[B]0.77	16.68	17.00	[a]	Zoloft	PF

SERTRALINE
Restricted benefit
Obsessive-compulsive disorder;

Panic disorder where other treatments have failed or are inappropriate.

8836C *NP*	Tablet 50 mg (as hydrochloride)	30	5	..	15.91	17.00	[a]	Auro-Sertraline 50	DO
							[a]	Eleva 50	AF
							[a]	Sertraline Pfizer	FZ
							[a]	Xydep 50	GN
				[B]0.77	16.68	17.00	[a]	Zoloft	PF
8837D *NP*	Tablet 100 mg (as hydrochloride)	30	5	..	15.91	17.00	[a]	Auro-Sertraline 100	DO
							[a]	Eleva 100	AF
							[a]	Sertraline Pfizer	FZ
							[a]	Xydep 100	GN
				[B]0.77	16.68	17.00	[a]	Zoloft	PF

Monoamine oxidase inhibitors, non-selective

PHENELZINE SULFATE
Caution
This drug is an irreversible monoamine oxidase inhibitor.

Restricted benefit
Depression where all other anti-depressant therapy has failed or is inappropriate.

2856H	Tablet 15 mg (base)	100	1	..	100.10	35.40		Nardil	LM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	TRANYLCYPROMINE SULFATE								
	Caution								
	This drug is an irreversible monoamine oxidase inhibitor.								
2444P	Tablet 10 mg (base)	50	2	..	33.55	34.64		Parnate	GH

Monoamine oxidase type A inhibitors

	MOCLOBEMIDE								
	Restricted benefit								
	Major depressive disorders.								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1900B *NP*	Tablet 150 mg	60	5	..	15.90	16.99	[a]	Amira 150	AF
							[a]	Chem mart Moclobemide	CH
							[a]	Clobemix	GM
							[a]	GenRx Moclobemide	GX
							[a]	Moclobemide Sandoz	SZ
							[a]	Mohexal	HX
							[a]	Terry White Chemists Moclobemide	TW
				[B]0.55	16.45	16.99	[a]	Aurorix	VP
8003F *NP*	Tablet 300 mg	60	5	..	24.67	25.76	[a]	Amira 300	AF
							[a]	Chem mart Moclobemide	CH
							[a]	Clobemix	GM
							[a]	GenRx Moclobemide	GX
							[a]	Moclobemide Sandoz	SZ
							[a]	Terry White Chemists Moclobemide	TW
				[B]1.10	25.77	25.76	[a]	Aurorix 300 mg	VP

Other antidepressants

	DESVENLAFAXINE SUCCINATE								
	Restricted benefit								
	Major depressive disorders.								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9366Y *NP*	Tablet 50 mg (base) (extended release)	28	5	..	43.31	35.40		Pristiq	PF
9367B *NP*	Tablet 100 mg (base) (extended release)	28	5	..	50.42	35.40		Pristiq	PF
	DULOXETINE HYDROCHLORIDE								
	Restricted benefit								
	Major depressive disorders.								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9155W *NP*	Capsule 30 mg (base)	28	..	..	38.22	35.40		Cymbalta	LY
9156X *NP*	Capsule 60 mg (base)	28	5	..	50.42	35.40		Cymbalta	LY
	LITHIUM CARBONATE **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
3059B *NP*	Tablet 250 mg	200	2	..	16.89	17.98		Lithicarb	AS
8290H *NP*	Tablet 450 mg (slow release)	200	2	..	*34.30	35.39		Quilonum SR	GK
	MIANSERIN HYDROCHLORIDE **Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy. **Restricted benefit** Severe depression. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1627P *NP*	Tablet 10 mg	50	5	..	15.38	16.47	a	Lumin 10	AF
				[B]3.30	18.68	16.47	a	Tolvon	MK
1628Q *NP*	Tablet 20 mg	50	5	..	25.34	26.43	a	Lumin 20	AF
				[B]3.30	28.64	26.43	a	Tolvon	MK
	MIRTAZAPINE **Restricted benefit** Major depressive disorders. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8513C *NP*	Tablet 30 mg	30	5	..	21.21	22.30	a	Aurozapine 30	DO
							a	Axit 30	AF
							a	Chem mart Mirtazapine	CH
							a	GenRx Mirtazapine	GX
							a	Mirtazapine-DP	GM
							a	Mirtazapine Sandoz	SZ
							a	Mirtazon	QA
							a	Terry White Chemists Mirtazapine	TW
				[B]2.60	23.81	22.30	a	Avanza	MK
8855C *NP*	Tablet 15 mg (orally disintegrating)	30	5	..	23.42	24.51	a	Avanza SolTab	MK
							a	Milivin OD 15	DO

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8856D *NP*	Tablet 30 mg (orally disintegrating)	30	5	..	29.10	30.19	a	Avanza SolTab	MK
							a	Milivin OD 30	DO
8857E *NP*	Tablet 45 mg (orally disintegrating)	30	5	..	40.60	35.40	a	Avanza SolTab	MK
							a	Milivin OD 45	DO
8883M *NP*	Tablet 45 mg	30	5	..	31.09	32.18	a	APO-Mirtazapine	TX
							a	Aurozapine 45	DO
							a	Axit 45	AF
							a	Chem mart Mirtazapine	CH
							a	Mirtazapine Sandoz	SZ
							a	Mirtazon	QA
							a	Terry White Chemists Mirtazapine	TW
				B2.84	33.93	32.18	a	Avanza	MK
9365X *NP*	Tablet 15 mg	30	5	..	16.28	17.37		Axit 15	AF

REBOXETINE MESILATE

Restricted benefit

Major depressive disorders.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8583R *NP*	Tablet 4 mg (base)	60	5	..	38.76	35.40		Edronax	PF

VENLAFAXINE HYDROCHLORIDE

Restricted benefit

Major depressive disorders.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8301X *NP*	Capsule 75 mg (base) (modified release)	28	5	..	37.71	35.40	a	Altven	FZ
							a	APO-Venlafaxine XR	TX
							a	Chem mart Venlafaxine XR	CH
							a	Efexor-XR	PF
							a	Elaxine SR 75	ZP
							a	Enlafax-XR	AF
							a	Terry White Chemists Venlafaxine XR	TW
							a	Venlafaxine generichealth XR	GQ
							a	Venlafaxine Sandoz XR	SZ
							a	Venla RBX	RA
							a	Venlexor XR	GM
8302Y *NP*	Capsule 150 mg (base) (modified release)	28	5	..	44.10	35.40	a	Altven	FZ
							a	APO-Venlafaxine XR	TX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Chem mart Venlafaxine XR	CH
							[a]	Efexor-XR	PF
							[a]	Elaxine SR 150	ZP
							[a]	Enlafax-XR	AF
							[a]	Terry White Chemists Venlafaxine XR	TW
							[a]	Venlafaxine generichealth XR	GQ
							[a]	Venlafaxine Sandoz XR	SZ
							[a]	Venla RBX	RA
							[a]	Venlexor XR	GM
8868R *NP*	Capsule 37.5 mg (base) (modified release)	28	..	..	24.15	25.24	[a]	Altven	FZ
							[a]	Efexor-XR	PF
							[a]	Elaxine SR 37.5	ZP
							[a]	Venla RBX	RA

Psychostimulants, agents used for ADHD and nootropics
Centrally acting sympathomimetics

ATOMOXETINE HYDROCHLORIDE

Authority required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where:
(a) treatment with dexamphetamine sulfate or methylphenidate hydrochloride poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information:
(1) The patient has a history of substance abuse or misuse (other than alcohol); and/or
(2) The patient has comorbid motor tics or Tourette's Syndrome; and/or
(3) The patient has comorbid severe anxiety diagnosed according to the DSM-IV; or

(b) treatment with dexamphetamine sulfate or methylphenidate hydrochloride has resulted in the development or worsening of a comorbid mood disorder (diagnosed according to the DSM-IV criteria i.e. anxiety disorder, obsessive compulsive disorder, depressive disorder) of a severity necessitating permanent stimulant treatment withdrawal; or where the combination of stimulant treatment with another agent would pose an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal; or

(c) treatment with dexamphetamine sulfate AND methylphenidate hydrochloride has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:
(1) Adverse effects on growth and weight; and/or
(2) Adverse effects on sleep including insomnia; and/or
(3) Adverse effects on appetite including anorexia.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Continuing sole PBS-subsidised treatment where the patient has previously been issued with an authority prescription for this drug.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9092M	Capsule 10 mg (base)	56	5	..	*221.18	35.40	Strattera	LY
9093N	Capsule 18 mg (base)	56	5	..	*221.18	35.40	Strattera	LY
9094P	Capsule 25 mg (base)	56	5	..	*221.18	35.40	Strattera	LY
9095Q	Capsule 40 mg (base)	56	5	..	*221.18	35.40	Strattera	LY
9096R	Capsule 60 mg (base)	56	5	..	*221.18	35.40	Strattera	LY
9289X	Capsule 80 mg (base)	28	5	..	147.11	35.40	Strattera	LY
9290Y	Capsule 100 mg (base)	28	5	..	147.11	35.40	Strattera	LY

DEXAMPHETAMINE SULFATE

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Authority required Use in attention deficit hyperactivity disorder, in accordance with State/Territory law; Narcolepsy. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1165H *NP*	Tablet 5 mg	100	5	..	18.19	19.28	Aspen Pharma Pty Ltd	QA
	METHYLPHENIDATE HYDROCHLORIDE **Note** Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride. **Authority required** Use in attention deficit hyperactivity disorder, in accordance with State/Territory law. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8839F *NP*	Tablet 10 mg	100	5	..	16.89	17.98	Ritalin 10	NV
	METHYLPHENIDATE HYDROCHLORIDE **Note** Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride. **Authority required** Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2172H *NP*	Tablet 27 mg (extended release)	30	5	..	55.46	35.40	Concerta	JC
2387P *NP*	Tablet 18 mg (extended release)	30	5	..	51.32	35.40	Concerta	JC
2388Q *NP*	Tablet 36 mg (extended release)	30	5	..	59.70	35.40	Concerta	JC
2432B *NP*	Tablet 54 mg (extended release)	30	5	..	69.76	35.40	Concerta	JC
	METHYLPHENIDATE HYDROCHLORIDE **Note** Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride. **Authority required** Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2276T *NP*	Capsule 20 mg (modified release)	30	5	..	44.57	35.40	Ritalin LA	NV
2280B *NP*	Capsule 30 mg (modified release)	30	5	..	52.03	35.40	Ritalin LA	NV

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
2283E *NP*	Capsule 40 mg (modified release)	30	5	..	54.56	35.40	Ritalin LA	NV
3440C *NP*	Capsule 10 mg (modified release)	30	5	..	34.04	35.13	Ritalin LA	NV

MODAFINIL

Note

Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.

Note

Any queries concerning the arrangements to prescribe modafinil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe modafinil should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:
(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or
(ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops.

The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:
(a) a psychiatric disorder;
(b) a cardiovascular disorder;
(c) a history of substance abuse;
(d) glaucoma;
(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:
Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:
(i) a definite history of cataplexy;
or
a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT). The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration;
or
an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and
(ii) absence of any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The authority application must be made in writing and must include the following:
(a) a completed authority prescription form; and
(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and
(c) details of the contraindication or intolerance to dexamphetamine sulfate; and
(d) either:
(i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
(ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug.

8816B	Tablet 100 mg	120	5	..	*346.98	35.40	Modavigil	CS

Anti-dementia drugs
Anticholinesterases

DONEPEZIL HYDROCHLORIDE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more. Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Note

Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8495D *NP*	Tablet 5 mg	28	5	..	155.45	35.40	Aricept	PF
8496E *NP*	Tablet 10 mg	28	5	..	155.45	35.40	Aricept	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

GALANTAMINE HYDROBROMIDE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Note

Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Nervous system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8770N *NP*	Capsule 8 mg (base) (prolonged release)	28	5	..	94.37	35.40	a	Galantyl	AF
							a	Reminyl	JC
8771P *NP*	Capsule 16 mg (base) (prolonged release)	28	5	..	114.01	35.40	a	Galantyl	AF
							a	Reminyl	JC
8772Q *NP*	Capsule 24 mg (base) (prolonged release)	28	5	..	134.64	35.40	a	Galantyl	AF
							a	Reminyl	JC

RIVASTIGMINE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment. The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing. Subsequent applications for continuing treatment can be made by telephone. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9161E *NP*	Transdermal patch 9 mg (releasing approximately 4.6 mg per 24 hours)	30	5	..	166.09	35.40	Exelon Patch 5	NV
9162F *NP*	Transdermal patch 18 mg (releasing approximately 9.5 mg per 24 hours)	30	5	..	166.09	35.40	Exelon Patch 10	NV

RIVASTIGMINE HYDROGEN TARTRATE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	(4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment; CONTINUING TREATMENT — Clinician assessed improvement. Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment. The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing. Subsequent applications for continuing treatment can be made by telephone. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8497F *NP*	Capsule 1.5 mg (base)	56	5	..	155.45	35.40	Exelon	NV
8498G *NP*	Capsule 3 mg (base)	56	5	..	155.45	35.40	Exelon	NV
8499H *NP*	Capsule 4.5 mg (base)	56	5	..	155.45	35.40	Exelon	NV
8500J *NP*	Capsule 6 mg (base)	56	5	..	155.45	35.40	Exelon	NV
8563Q *NP*	Oral solution 2 mg (base) per mL, 120 mL	‡1	5	..	155.45	35.40	Exelon	NV

Other anti-dementia drugs

MEMANTINE HYDROCHLORIDE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 to 14.
Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 to 14.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 to 14 for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Patients who qualify under this criterion are from 1 or more of the following groups: (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment; CONTINUING TREATMENT — Clinician assessed improvement. Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment. The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing. Subsequent applications for continuing treatment can be made by telephone. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1956Y *NP*	Tablet 10 mg	56	5	..	106.95	35.40	a	APO-Memantine	TX
							a	Ebixa	LU
							a	Memanxa	QA
9306T *NP*	Tablet 20 mg	28	5	..	106.95	35.40		Ebixa	LU

Other nervous system drugs

Parasympathomimetics

Anticholinesterases

PYRIDOSTIGMINE BROMIDE

1959D	Tablet 60 mg	150	5	..	71.32	35.40		Mestinon	VT
2608G	Tablet 180 mg (modified release)	100	5	..	*149.22	35.40		Mestinon Timespan	VT
2724J	Tablet 10 mg	100	5	..	*23.00	24.09		Mestinon	VT

Choline esters

BETHANECHOL CHLORIDE

1062X *NP*	Tablet 10 mg	100	2	..	21.03	22.12		Uro-Carb	YN

Drugs used in addictive disorders

Drugs used in nicotine dependence

BUPROPION HYDROCHLORIDE

Note

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Authority required

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and:
(a) who has entered a comprehensive support and counselling program; or

(b) who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.

Details of the program must be specified in the authority application.

8465M *NP*	Tablet 150 mg (sustained release)	30	..	..	73.09	35.40	a	Prexaton	GM
				B0.80	73.89	35.40	a	Zyban	GK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	BUPROPION HYDROCHLORIDE								
	Note								
	Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.								
	Authority required								
	Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.								
8710K *NP*	Tablet 150 mg (sustained release)	90	..	..	158.99	35.40	a	Prexaton	GM
				[B]0.81	159.80	35.40	a	Zyban	GK
	NICOTINE								
	Authority required								
	Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy.								
	Note								
	Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised. Benefit is improved if used in conjunction with a comprehensive support and counselling program.								
	Authority required								
	Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the initial authority application;								
	Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the initial authority application.								
	Note								
	A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised.								
5465P *NP*	Transdermal patch releasing approximately 21 mg per 24 hours	28	2	..	55.22	35.40		Nicabate P	GC
9198D *NP*	Transdermal patch releasing approximately 15 mg per 16 hours	28	2	..	55.22	35.40		Nicorette Patch	JT
	NICOTINE								
	Authority required								
	Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the initial authority application;								
	Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the initial authority application.								
	Note								
	No applications for increased maximum quantities will be authorised. Applications for increased repeats, up to a maximum of 2, may be authorised. A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year.								
3414Q *NP*	Transdermal patch releasing approximately 21 mg per 24 hours	28	..	..	55.22	35.40		Nicotinell Step 1	NC
5572G *NP*	Transdermal patch releasing approximately 14 mg per 24 hours	28	..	..	55.22	35.40		Nicotinell Step 2	NC
5573H *NP*	Transdermal patch releasing approximately 7 mg per 24 hours	28	..	..	55.22	35.40		Nicotinell Step 3	NC

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	NICOTINE **Authority required** Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy. **Note** Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised. Benefit is improved if used in conjunction with a comprehensive support and counselling program.							
5571F *NP*	Transdermal patch releasing approximately 21 mg per 24 hours	28	2	..	55.22	35.40	Nicotinell Step 1	NC
	VARENICLINE **Note** A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. **Authority required** Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and: (a) who has entered a comprehensive support and counselling program; or (b) who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the authority application.							
9128K *NP*	Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack	‡1	..	..	103.12	35.40	Champix	PF
	VARENICLINE **Note** A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. **Authority required** Continuation of short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.							
9129L *NP*	Tablet 1 mg (as tartrate)	112	..	..	*231.70	35.40	Champix	PF
	VARENICLINE **Note** A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. **Authority required** Completion of short-term sole PBS-subsidised therapy as an aid to achieving long-term abstinence after completion of an initial 12-week PBS-subsidised course in a patient who has ceased smoking, and who is enrolled in a comprehensive support and counselling program.							
5469W *NP*	Tablet 1 mg (as tartrate)	56	2	..	120.42	35.40	Champix	PF

Drugs used in alcohol dependence

ACAMPROSATE CALCIUM
Authority required (STREAMLINED)
2665
For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8357W *NP*	Tablet 333 mg (enteric coated)	180	1	..	166.58	35.40		Campral	AF
	NALTREXONE HYDROCHLORIDE								
	Caution								
	Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.								
	Authority required								
	For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8370M *NP*	Tablet 50 mg	30	1	..	135.67	35.40	[a]	Naltrexone generichealth	GQ
							[a]	ReVia	BQ

Other nervous system drugs
Other nervous system drugs

	RILUZOLE								
	Authority required								
	Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who: (1) are ambulatory, and (a) have not undergone tracheostomy, and (b) have not experienced respiratory failure; OR (2) are not ambulatory, and (a) have not undergone tracheostomy, and (b) have not experienced respiratory failure, and (c) are either able to use upper limbs or able to swallow. The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.								
	Authority required								
	Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who: (1) are ambulatory, and (a) have not undergone tracheostomy, and (b) have not experienced respiratory failure; OR (2) are not ambulatory, and (a) have not undergone tracheostomy, and (b) have not experienced respiratory failure, and (c) are either able to use upper limbs or able to swallow.								
	Note								
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8664B *NP*	Tablet 50 mg	56	5	..	662.00	35.40		Rilutek	SW
	TETRABENAZINE								
	Authority required (STREAMLINED)								
	1161 Hyperkinetic extrapyramidal disorders.								
	Note								
	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1330B *NP*	Tablet 25 mg	112	5	..	337.55	35.40		Orphan Australia Pty Ltd	OA

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Antiparasitic products, insecticides and repellents

Antiprotozoals

Agents against amoebiasis and other protozoal diseases

Nitroimidazole derivatives

METRONIDAZOLE

1636D *NP*	Tablet 200 mg	21	1	..	7.88	8.97	a	Metrogyl 200	AF
							a	Metronide 200	AV
				B2.30	10.18	8.97	a	Flagyl	SW
1642K *NP*	Suppositories 500 mg, 10	‡1	..	..	23.16	24.25		Flagyl	SW

METRONIDAZOLE
Restricted benefit
Treatment of anaerobic infections.

1621H *NP*	Tablet 400 mg	21	1	..	9.85	10.94	a	Metrogyl 400	AF
							a	Metronide 400	AV
				B2.30	12.15	10.94	a	Flagyl	SW

METRONIDAZOLE BENZOATE

1630T *NP*	Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡1	..	..	18.82	19.91		Flagyl S	SW

TINIDAZOLE

1465D *NP*	Tablet 500 mg	4	..	..	10.79	11.88	a	Simplotan	FZ
				B2.42	13.21	11.88	a	Fasigyn	PF

Other agents against amoebiasis and other protozoal diseases

ATOVAQUONE
Authority required (STREAMLINED)
1433
Treatment of mild to moderate Pneumocystis carinii pneumonia in adult patients who are intolerant of trimethoprim/sulfamethoxazole therapy.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8300W *NP*	Oral suspension 750 mg per 5 mL, 210 mL	‡1	..	..	1034.57	35.40		Wellvone	GK

PYRIMETHAMINE

1966L *NP*	Tablet 25 mg	50	..	..	16.37	17.46		Daraprim	GK

Antimalarials

Biguanides

ATOVAQUONE with PROGUANIL HYDROCHLORIDE
Authority required
Treatment of suspected or confirmed Plasmodium falciparum malaria in a patient aged 3 years or older where quinine containing regimens are inappropriate.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Atovaquone with proguanil hydrochloride is not PBS-subsidised for the prophylaxis of malaria.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9439T *NP*	Tablet 250 mg-100 mg	12	..	..	67.00	35.40	Malarone	GK

Methanolquinolines

QUINININE SULFATE
Caution
Severe thrombocytopenia has been reported with this drug.

Authority required (STREAMLINED)
2142
Malaria.

1975Y *NP*	Tablet 300 mg	50	2	..	14.14	15.23	Quinate	AS

Artemisinin and derivatives, combinations

ARTEMETHER with LUMEFANTRINE
Authority required
Treatment of suspected or confirmed malaria due to Plasmodium falciparum.

Note
Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

9498X	Tablet 20 mg-120 mg	24	..	..	96.90	35.40	Riamet	NV

ARTEMETHER with LUMEFANTRINE
Authority required
Treatment of suspected or confirmed malaria due to Plasmodium falciparum in a patient unable to swallow a solid dosage form of artemether with lumefantrine.

Note
Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

5296R	Tablet (dispersible) 20 mg-120 mg	18	..	..	96.90	35.40	Riamet 20mg/120mg Dispersible	NV

Anthelmintics

Antitrematodals

Quinoline derivatives and related substances

PRAZIQUANTEL
Authority required (STREAMLINED)
3147
Schistosomiasis.

9447F *NP*	Tablet 600 mg	8	..	..	40.85	35.40	Biltricide	BN

Antinematodal agents

Benzimidazole derivatives

ALBENDAZOLE
Authority required (STREAMLINED)
2446
Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person;

Antiparasitic products, insecticides and repellents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	1388 Strongyloidiasis; ***3241*** Treatment of hookworm infestation.							
9047E *NP*	Tablet 200 mg	6	..	..	33.10	34.19	Zentel	GK
	ALBENDAZOLE **Authority required (STREAMLINED)** ***1525*** Treatment of tapeworm infestation.							
8503M *NP*	Tablet 200 mg	6	1	..	33.10	34.19	Zentel	GK
	ALBENDAZOLE **Authority required (STREAMLINED)** ***1496*** For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used.							
8459F	Tablet 400 mg	60	2	..	185.25	35.40	Eskazole	GK

Tetrahydropyrimidine derivatives

PYRANTEL EMBONATE

3047J *NP*	Tablet 125 mg (base)	6	..	..	14.60	15.69	Anthel 125	AF
3048K *NP*	Tablet 250 mg (base)	6	..	..	22.77	23.86	Anthel 250	AF

Avermectines

IVERMECTIN
Authority required (STREAMLINED)
1242
Onchocerciasis;
1388
Strongyloidiasis.

8359Y *NP*	Tablet 3 mg	4	..	..	31.31	32.40	Stromectol	MK

Ectoparasiticides, incl. scabicides, insecticides and repellents

Ectoparasiticides, incl. scabicides

Pyrethrines, incl. synthetic compounds

PERMETHRIN

3054R *NP*	Cream 50 mg per g (5%), 30 g	‡1	1	..	16.77	17.86	Lyclear	JT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Respiratory system

Nasal preparations

Decongestants and other nasal preparations for topical use

Other nasal preparations

MUPIROCIN

Authority required (STREAMLINED)

3136

Nasal colonisation with Staphylococcus aureus in an Aboriginal or a Torres Strait Islander person.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9440W *NP*	Nasal ointment 20 mg (as calcium) per g (2%), 3 g	‡1	..	..	20.63	21.72		Bactroban	GK

Drugs for obstructive airway diseases

Adrenergics, inhalants

Selective beta-2-adrenoceptor agonists

EFORMOTEROL FUMARATE DIHYDRATE

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids;

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids.

8136F *NP*	Capsule containing powder for oral inhalation 12 micrograms (for use in Foradile Aerolizer)	60	5	..	37.33	35.40		Foradile	NV
8239P *NP*	Powder for oral inhalation in breath actuated device 6 micrograms per dose (60 doses)	‡1	5	..	26.38	27.47		Oxis Turbuhaler	AP
8240Q *NP*	Powder for oral inhalation in breath actuated device 12 micrograms per dose (60 doses)	‡1	5	..	36.44	35.40		Oxis Turbuhaler	AP

INDACATEROL

Restricted benefit

Chronic obstructive pulmonary disease.

Note

Indacaterol is not PBS-subsidised for the treatment of asthma.

5134F *NP*	Capsule containing powder for oral inhalation 150 micrograms (as maleate) (for use in Breezhaler)	30	5	..	73.44	35.40		Onbrez	NV
5137J *NP*	Capsule containing powder for oral inhalation 300 micrograms (as maleate) (for use in Breezhaler)	30	5	..	73.44	35.40		Onbrez	NV

SALBUTAMOL SULFATE

1099W *NP*	Capsule containing powder for oral inhalation 200 micrograms (base) (for use in Ventolin Rotahaler)	200	5	..	*16.06	17.15		Ventolin Rotacaps	GK
8288F *NP*	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	*13.82	14.91	[a]	Airomir	IA
							[a]	APO-Salbutamol Inhaler	TX
							[a]	Asmol CFC-free	AL
				[B]2.32	*16.14	14.91	[a]	Ventolin CFC-free	GK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	SALBUTAMOL SULFATE **Restricted benefit** Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.								
8354Q *NP*	Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	*38.60	35.40		Airomir Autohaler	IA
	SALBUTAMOL SULFATE **Restricted benefit** Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer; Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer.								
2000G *NP*	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	2	5	..	*18.32	19.41	[a]	Asmol 2.5 uni-dose	AF
							[a]	Butamol 2.5	QA
							[a]	GenRx Salbutamol	GX
							[a]	Pharmacor Salbutamol 2.5	CR
							[a]	Salbutamol-GA	GM
							[a]	Salbutamol Sandoz	SZ
				[B]1.34	*19.66	19.41	[a]	Ventolin Nebules	GK
2001H *NP*	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	2	5	..	*18.98	20.07	[a]	Asmol 5 uni-dose	AF
							[a]	Butamol 5	QA
							[a]	GenRx Salbutamol	GX
							[a]	Pharmacor Salbutamol 5	CR
							[a]	Salbutamol-GA	GM
							[a]	Salbutamol Sandoz	SZ
				[B]1.36	*20.34	20.07	[a]	Ventolin Nebules	GK
2003K *NP*	Nebuliser solution 5 mg (base) per mL (0.5%), 30 mL	2	2	..	*18.98	20.07		Pfizer Australia Pty Ltd	PF
	SALMETEROL XINAFOATE **Restricted benefit** Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids; Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids.								
8141L *NP*	Powder for oral inhalation in breath actuated device 50 micrograms (base) per dose (60 doses)	‡1	5	..	37.33	35.40		Serevent Accuhaler	GK
	TERBUTALINE SULFATE								
1252X *NP*	Powder for oral inhalation in breath actuated device 500 micrograms per dose (200 doses)	‡1	5	..	17.83	18.92		Bricanyl Turbuhaler	AP

Adrenergics and other drugs for obstructive airway diseases

BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE
Restricted benefit
Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with oral corticosteroids;

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with inhaled corticosteroids;

Respiratory system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	For maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and a long-acting beta-2 agonist.							
8625Y *NP*	Powder for oral inhalation in breath actuated device 200 micrograms-6 micrograms per dose (120 doses)	‡1	5	..	58.77	35.40	Symbicort Turbuhaler 200/6	AP
8796Y *NP*	Powder for oral inhalation in breath actuated device 100 micrograms-6 micrograms per dose (120 doses)	‡1	5	..	54.47	35.40	Symbicort Turbuhaler 100/6	AP

BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE

Restricted benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide.

Note

Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Restricted benefit

Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy.

Note

Budesonide with eformoterol fumarate dihydrate is not indicated for the initiation of bronchodilator therapy in COPD.

8750M *NP*	Powder for oral inhalation in breath actuated devices 400 micrograms-12 micrograms per dose (60 doses), 2	1	5	..	90.55	35.40	Symbicort Turbuhaler 400/12	AP

FLUTICASONE PROPIONATE with SALMETEROL XINAFOATE

Restricted benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate.

8430Q *NP*	Powder for oral inhalation in breath actuated device 100 micrograms-50 micrograms (base) per dose (60 doses)	‡1	5	..	47.20	35.40	Seretide Accuhaler 100/50	GK
8431R *NP*	Powder for oral inhalation in breath actuated device 250 micrograms-50 micrograms (base) per dose (60 doses)	‡1	5	..	59.31	35.40	Seretide Accuhaler 250/50	GK
8517G *NP*	Oral pressurised inhalation 50 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation	‡1	5	..	47.20	35.40	Seretide MDI 50/25	GK
8518H *NP*	Oral pressurised inhalation 125 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation	‡1	5	..	59.31	35.40	Seretide MDI 125/25	GK

FLUTICASONE PROPIONATE with SALMETEROL XINAFOATE

Restricted benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;

Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy.

Note

Seretide is not indicated for the initiation of bronchodilator therapy in COPD.

8432T *NP*	Powder for oral inhalation in breath actuated device 500 micrograms-50 micrograms (base) per dose (60 doses)	‡1	5	..	78.44	35.40	Seretide Accuhaler 500/50	GK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
8519J *NP*	Oral pressurised inhalation 250 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation	‡1	5	..	78.44	35.40	Seretide MDI 250/25	GK

Other drugs for obstructive airway diseases, inhalants

Glucocorticoids

BECLOMETHASONE DIPROPIONATE

8406K *NP*	Oral pressurised inhalation 50 micrograms per dose (200 doses), CFC-free formulation	‡1	5	..	19.29	20.38	Qvar 50	IA
8407L *NP*	Oral pressurised inhalation 100 micrograms per dose (200 doses), CFC-free formulation	‡1	5	..	33.46	34.55	Qvar 100	IA

BECLOMETHASONE DIPROPIONATE
Restricted benefit
Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

8408M *NP*	Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation	‡1	5	..	27.87	28.96	Qvar 50 Autohaler	IA
8409N *NP*	Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation	‡1	5	..	39.13	35.40	Qvar 100 Autohaler	IA

BUDESONIDE

2070Y *NP*	Powder for oral inhalation in breath actuated device 100 micrograms per dose (200 doses)	‡1	5	..	23.34	24.43	Pulmicort Turbuhaler	AP
2071B *NP*	Powder for oral inhalation in breath actuated device 200 micrograms per dose (200 doses)	‡1	5	..	31.08	32.17	Pulmicort Turbuhaler	AP
2072C *NP*	Powder for oral inhalation in breath actuated device 400 micrograms per dose (200 doses)	‡1	5	..	45.84	35.40	Pulmicort Turbuhaler	AP

BUDESONIDE
Authority required (STREAMLINED)
1351
Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy.

2065Q *NP*	Nebuliser suspension single dose units 500 micrograms in 2 mL, 30	‡1	5	..	37.86	35.40	Pulmicort Respules	AP
2066R *NP*	Nebuliser suspension single dose units 1 mg in 2 mL, 30	‡1	5	..	49.00	35.40	Pulmicort Respules	AP

CICLESONIDE

8853Y *NP*	Oral pressurised inhalation 80 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	26.15	27.24	Alvesco 80	NQ
8854B *NP*	Oral pressurised inhalation 160 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	42.25	35.40	Alvesco 160	NQ

FLUTICASONE PROPIONATE

8147T *NP*	Powder for oral inhalation in breath actuated device 100 micrograms per dose (60 doses)	‡1	5	..	17.09	18.18	Flixotide Junior Accuhaler	GK
8148W *NP*	Powder for oral inhalation in breath actuated device 250 micrograms per dose (60 doses)	‡1	5	..	30.66	31.75	Flixotide Accuhaler	GK
8149X *NP*	Powder for oral inhalation in breath actuated device 500 micrograms per dose (60 doses)	‡1	1	..	49.72	35.40	Flixotide Accuhaler	GK
8345F *NP*	Oral pressurised inhalation 125 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	30.66	31.75	Flixotide	GK
8346G *NP*	Oral pressurised inhalation 250 micrograms per dose (120 doses), CFC-free formulation	‡1	1	..	49.72	35.40	Flixotide	GK
8516F *NP*	Oral pressurised inhalation 50 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	17.09	18.18	Flixotide Junior	GK

Respiratory system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Anticholinergics								
	IPRATROPIUM BROMIDE								
8671J *NP*	Oral pressurised inhalation 21 micrograms per dose (200 doses), CFC-free formulation	2	5	..	*33.84	34.93		Atrovent	BY
	IPRATROPIUM BROMIDE								
	Restricted benefit								
	Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer;								
	Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer.								
1542E *NP*	Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30	2	5	..	*35.74	35.40	[a]	Aeron 250	QA
							[a]	APO-Ipratropium	TX
							[a]	Ipratrin	AF
							[a]	Ipravent	PF
				[B]0.68	*36.42	35.40	[a]	Atrovent	BY
8238N *NP*	Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30	2	5	..	*41.06	35.40	[a]	Aeron 500	QA
							[a]	APO-Ipratropium	TX
							[a]	Ipratrin Adult	AF
							[a]	Ipravent	PF
				[B]0.58	*41.64	35.40	[a]	Atrovent Adult	BY
	TIOTROPIUM BROMIDE MONOHYDRATE								
	Restricted benefit								
	Chronic obstructive pulmonary disease.								
8626B *NP*	Capsule containing powder for oral inhalation 18 micrograms (base) (for use in HandiHaler)	30	5	..	76.89	35.40		Spiriva	BY
	Antiallergic agents, excl. corticosteroids								
	NEDOCROMIL SODIUM								
8365G *NP*	Oral pressurised inhalation 2 mg per dose (112 doses), CFC-free formulation	‡1	5	..	37.69	35.40		Tilade CFC-Free	SW
	SODIUM CROMOGLYCATE								
2878L *NP*	Capsule containing powder for oral inhalation 20 mg (for use in Intal Spinhaler or Intal Halermatic)	100	5	..	31.41	32.50		Intal Spincaps	GM
8334P *NP*	Oral pressurised inhalation 5 mg per dose (112 doses), CFC-free formulation	‡1	5	..	35.84	35.40		Intal Forte CFC-Free	SW
8767K *NP*	Oral pressurised inhalation 1 mg per dose (200 doses), CFC-free formulation	‡1	5	..	30.29	31.38		Intal CFC-Free	SW
	Adrenergics for systemic use								
	Alpha- and beta-adrenoceptor agonists								
	ADRENALINE								
1016L *NP*	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	20.34	21.43		Link Medical Products Pty Ltd	LM
	ADRENALINE								
	Authority required								
	Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who: (a) has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply; or								
	(b) has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis;								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Continuing sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug.							
	Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)							
	Note Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time. No repeats will be issued.							
	Caution EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.							
3408J *NP*	I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40	Anapen Junior	LM
3409K *NP*	I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40	Anapen	LM
8697R *NP*	I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40	EpiPen Jr.	AL
8698T *NP*	I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	106.00	35.40	EpiPen	AL

Selective beta-2-adrenoceptor agonists

SALBUTAMOL SULFATE

1103C *NP*	Syrup 2 mg (base) per 5 mL, 150 mL	2	5	..	*22.20	23.29	Ventolin	GK

TERBUTALINE SULFATE

1034K *NP*	Injection 500 micrograms in 1 mL	5	..	..	30.59	31.68	Bricanyl	AP

Other systemic drugs for obstructive airway diseases

Xanthines

THEOPHYLLINE

Caution

Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2614N *NP*	Syrup 133.3 mg per 25 mL, 500 mL	‡1	5	..	12.31	13.40	Nuelin	IA
2634P *NP*	Tablet 250 mg (sustained release)	100	5	..	13.32	14.41	Nuelin-SR 250	IA
8230E *NP*	Tablet 200 mg (sustained release)	100	5	..	12.16	13.25	Nuelin-SR 200	IA
8231F *NP*	Tablet 300 mg (sustained release)	100	5	..	14.70	15.79	Nuelin-SR 300	IA

Leukotriene receptor antagonists

MONTELUKAST SODIUM

Authority required (STREAMLINED)

2617

First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.

Note

Montelukast sodium is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Montelukast sodium is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to montelukast sodium.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
8627C *NP*	Chewable tablet 4 mg (base)	28	5	..	47.93	35.40	Singulair	MK
	MONTELUKAST SODIUM **Authority required (STREAMLINED)** ***2618*** First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.							
	Authority required (STREAMLINED) ***3217*** Prevention of exercise-induced asthma, as an alternative to adding salmeterol xinafoate or eformoterol fumarate, in a child aged 6 to 14 years whose asthma is otherwise well controlled while receiving optimal dose inhaled corticosteroid, but who requires short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.							
	Note Montelukast sodium is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
8628D *NP*	Chewable tablet 5 mg (base)	28	5	..	45.71	35.40	Singulair	MK

Cough and cold preparations

Cough suppressants, excl. combinations with expectorants

Opium alkaloids and derivatives

	CODEINE PHOSPHATE							
1214X *NP*	Tablet 30 mg	20	..	..	16.87	17.96	Fawns and McAllan Proprietary Limited	FM

Antihistamines for systemic use

Antihistamines for systemic use

Phenothiazine derivatives

	PROMETHAZINE HYDROCHLORIDE							
1948M *NP*	Injection 50 mg in 2 mL	10	..	..	*22.32	23.41	Hospira Pty Limited	HH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Sensory organs								
	Ophthalmologicals								
	Antiinfectives								
	Antibiotics								
	AZITHROMYCIN **Restricted benefit** Trachoma.								
	Note No applications for increased maximum quantities and/or repeats will be authorised.								
8201P *NP*	Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL	‡1	..	..	#21.14	22.58		Zithromax	PF
8336R *NP*	Tablet 500 mg (as dihydrate)	2	2	..	21.09	22.18	[a]	Azithromycin Sandoz	SZ
							[a]	Zithromax	PF
							[a]	Zitrocin	GM
	CHLORAMPHENICOL								
1171P *NP,MW*	Eye ointment 10 mg per g (1%), 4 g	‡1	..	..	9.76	10.85		Chloromycetin	PF
								Chlorsig	QA
2360F *NP,MW*	Eye drops 5 mg per mL (0.5%), 10 mL	‡1	2	..	11.00	12.09		Chloromycetin	PF
								Chlorsig	QA
	GENTAMICIN SULFATE **Restricted benefit** Invasive ocular infection; Perioperative use in ophthalmic surgery; Suspected pseudomonal eye infection.								
1441W	Eye drops 3 mg (base) per mL (0.3%), 5 mL	‡1	2	..	18.29	19.38		Genoptic	AG
	TOBRAMYCIN **Restricted benefit** Invasive ocular infection; Perioperative use in ophthalmic surgery; Suspected pseudomonal eye infection.								
2328M	Eye drops 3 mg per mL (0.3%), 5 mL	‡1	2	..	19.28	20.37		Tobrex	AQ
2329N	Eye ointment 3 mg per g (0.3%), 3.5 g	‡1	..	..	22.38	23.47		Tobrex	AQ
	Antivirals								
	ACICLOVIR **Restricted benefit** Herpes simplex keratitis.								
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1002R *NP*	Eye ointment 30 mg per g (3%), 4.5 g	‡1	..	..	33.63	34.72		Zovirax	GK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Other antiinfectives							
	CIPROFLOXACIN **Authority required** Bacterial keratitis.							
1217C	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	..	*28.48	29.57 [a]	CiloQuin	IQ
				[B]2.06	*30.54	29.57 [a]	Ciloxan	AQ
	OFLOXACIN **Authority required** Bacterial keratitis.							
8383F	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	..	*32.14	33.23	Ocuflox	AG
	Antiinflammatory agents							
	Corticosteroids, plain							
	DEXAMETHASONE							
1288T *NP*	Eye drops 1 mg per mL (0.1%), 5 mL	‡1	2	..	10.61	11.70	Maxidex	AQ
	FLUOROMETHOLONE							
1204J *NP*	Eye drops 1 mg per mL (0.1%), 5 mL	‡1	5	..	10.61	11.70	Flucon	AQ
							FML Liquifilm	AG
	FLUOROMETHOLONE ACETATE							
1438Q *NP*	Eye drops 1 mg per mL (0.1%), 5 mL	‡1	2	..	10.61	11.70	Flarex	AQ
	HYDROCORTISONE ACETATE							
2441L *NP*	Eye ointment 10 mg per g (1%), 5 g	‡1	..	..	12.69	13.78	Hycor	QA
	Corticosteroids and mydriatics in combination							
	PREDNISOLONE ACETATE with PHENYLEPHRINE HYDROCHLORIDE **Restricted benefit** Corneal grafts; Uveitis.							
3112T *NP*	Eye drops 10 mg-1.2 mg per mL (1%-0.12%), 10 mL	‡1	2	..	23.73	24.82	Prednefrin Forte	AG
	Antiinflammatory agents, non-steroids							
	FLURBIPROFEN SODIUM							
8699W *NP*	Eye drops 300 micrograms per mL (0.03%), single dose units 0.4 mL, 5	1	..	..	16.82	17.91	Ocufen	AG
	Antiglaucoma preparations and miotics							
	Sympathomimetics in glaucoma therapy							
	APRACLONIDINE HYDROCHLORIDE **Restricted benefit** Short-term reduction of intra-ocular pressure in patients already on maximally tolerated anti-glaucoma therapy.							
8083K	Eye drops 5 mg (base) per mL (0.5%), 10 mL	‡1	2	..	41.77	35.40	Iopidine 0.5%	AQ
	BRIMONIDINE TARTRATE							
5298W	Eye drops 1.5 mg per mL (0.15%), 5 mL	‡1	5	..	20.14	21.23	Alphagan P 1.5	AG

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
8351M	Eye drops 2 mg per mL (0.2%), 5 mL	‡1	5	..	20.14	21.23	a	Enidin	PE
				B1.63	21.77	21.23	a	Alphagan	AG

BRIMONIDINE TARTRATE with TIMOLOL MALEATE

Restricted benefit

Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;

Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.

8826M	Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL	‡1	5	..	26.03	27.12		Combigan	AG

Parasympathomimetics

PILOCARPINE HYDROCHLORIDE

2595N	Eye drops 10 mg per mL (1%), 15 mL	‡1	5	..	12.53	13.62		Isopto Carpine	AQ
2596P	Eye drops 20 mg per mL (2%), 15 mL	‡1	5	..	13.78	14.87		Isopto Carpine	AQ
2598R	Eye drops 40 mg per mL (4%), 15 mL	‡1	5	..	16.63	17.72		Isopto Carpine	AQ

Carbonic anhydrase inhibitors

ACETAZOLAMIDE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1004W *NP*	Tablet 250 mg	100	3	..	23.79	24.88		Diamox	QA

BRINZOLAMIDE

8483L	Eye drops 10 mg per mL (1%), 5 mL	‡1	5	..	22.77	23.86	a	BrinzoQuin	IQ
				B1.18	23.95	23.86	a	Azopt	AQ

BRINZOLAMIDE with TIMOLOL MALEATE

Restricted benefit

Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;

Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.

3438Y	Eye drops 10 mg-5 mg (base) per mL (1%-0.5%), 5 mL	‡1	5	..	26.88	27.97		Azarga	AQ

DORZOLAMIDE HYDROCHLORIDE

8488R	Eye drops 20 mg (base) per mL (2%), 5 mL	‡1	5	..	21.29	22.38		Trusopt	MK

DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE

Restricted benefit

Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;

Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.

8567X	Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL	‡1	5	..	27.18	28.27		Cosopt	MK

Beta blocking agents

BETAXOLOL HYDROCHLORIDE

2811Y	Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL	‡1	5	..	14.77	15.86		Betoptic S	AQ
2825Q	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	‡1	5	..	14.77	15.86	a	BetoQuin	IQ
				B2.09	16.86	15.86	a	Betoptic	AQ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	TIMOLOL MALEATE							
1278G	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	‡1	5	..	11.54	12.63 [a]	Tenopt	QA
				[B]3.03	14.57	12.63 [a]	Timoptol	FR
1279H	Eye drops 5 mg (base) per mL (0.5%), 5 mL	‡1	5	..	12.31	13.40 [a]	Tenopt	QA
				[B]3.03	15.34	13.40 [a]	Timoptol	FR
1925H	Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL	‡1	5	..	11.54	12.63	Timoptol XE	MK
1926J	Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL	‡1	5	..	12.31	13.40	Timoptol XE	MK
8803H	Eye gel 1 mg (base) per g (0.1%), 5 g	‡1	5	..	12.87	13.96	Nyogel	NV

Prostaglandin analogues

	BIMATOPROST							
8620Q	Eye drops 300 micrograms per mL (0.03%), 3 mL	‡1	5	..	42.14	35.40	Lumigan	AG
	BIMATOPROST with TIMOLOL MALEATE							
	Restricted benefit							
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;							
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.							
9464D	Eye drops 300 micrograms-5 mg (base) per mL (0.03%-0.5%), 3 mL	‡1	5	..	46.59	35.40	Ganfort 0.3/5	AG
	LATANOPROST							
8243W	Eye drops 50 micrograms per mL (0.005%), 2.5 mL	‡1	5	..	42.14	35.40	Xalatan	PF
	LATANOPROST with TIMOLOL MALEATE							
	Restricted benefit							
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;							
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.							
8895E	Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL	‡1	5	..	46.59	35.40	Xalacom	PF
	TRAVOPROST							
8597L	Eye drops 40 micrograms per mL (0.004%), 2.5 mL	‡1	5	..	42.14	35.40	Travatan	AQ
	TRAVOPROST with TIMOLOL MALEATE							
	Restricted benefit							
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;							
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.							
9057Q	Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL	‡1	5	..	46.59	35.40	Duotrav	AQ

Mydriatics and cycloplegics

Anticholinergics

	ATROPINE							
1093M *NP*	Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL	‡1	2	..	21.77	22.86	Atropt	QA
	HOMATROPINE HYDROBROMIDE							
2541R *NP*	Eye drops 20 mg per mL (2%), 15 mL	‡1	2	..	18.81	19.90	Isopto Homatropine	AQ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Decongestants and antiallergics								
	Other antiallergics								
	SODIUM CROMOGLYCATE								
	Restricted benefit								
	Vernal kerato-conjunctivitis.								
1127H	Eye drops 20 mg per mL (2%), 10 mL	‡1	5	..	14.21	15.30	a	Cromolux	AE
NP							a	Opticrom	SW
	Ocular vascular disorder agents								
	Antineovascularisation agents								
	RANIBIZUMAB								
	Authority required								
	Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography.								
	Where a fluoroscein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.								
	Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.								
	The first authority application for each eye must be made in writing, and must include: (a) a completed authority prescription form; and (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and (c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.								
	Written applications for authority to prescribe ranibizumab should be forwarded to:								
	Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001								
	Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.								
	Authority required								
	Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.								
	Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
1382R	Solution for intravitreal injection 2.3 mg in 0.23 mL	1	2	..	1976.36	35.40		Lucentis	NV
	VERTEPORFIN								
	Authority required								
	Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).								
	Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.								
	The first authority application for each eye must be made in writing, and must include: (a) a completed authority prescription form; and (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).								
	Written applications for authority to prescribe verteporfin should be forwarded to:								
	Medicare Australia								

Sensory organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained. No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised. Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum. **Authority required** Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program. Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. The first authority application for each eye must be made in writing, and must include: (a) a completed authority prescription form; and (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%). Written applications for authority to prescribe verteporfin should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained. A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS. Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum. **Authority required** Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye. A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS. Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum. Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
1349B	Powder for I.V. infusion 15 mg	1	..	..	2246.36	35.40	Visudyne	NV

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Other ophthalmologicals									
Other ophthalmologicals									
	CARBOMER **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome.								
8384G *NP*	Eye gel 2 mg per g (0.2%), 10 g	‡1	5	..	10.27	11.36		GelTears	BU
							[a]	PAA	NM
				[B]1.50	11.77	11.36	[a]	Viscotears	NV
	CARBOMER **Restricted benefit** For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. **Note** No applications for increased maximum quantities and/or repeats will be authorised.								
9210R	Eye gel 2 mg per g (0.2%), 10 g	‡1	11	..	10.27	11.36		GelTears	BU
							[a]	PAA	NM
				[B]1.50	11.77	11.36	[a]	Viscotears	NV
	CARBOMER **Authority required (STREAMLINED)** ***1359*** Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
8578L *NP*	Eye gel 2 mg per g (0.2%), single dose units 0.6 mL, 30	3	5	..	*36.09	35.40		Viscotears Gel PF	NV
	CARBOMER 974 **Authority required (STREAMLINED)** ***1359*** Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
8514D *NP*	Ocular lubricating gel 3 mg per g (0.3%), single dose units 0.5 g, 30	3	5	..	*36.06	35.40		Poly Gel	AQ
	CARMELLOSE SODIUM **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome.								
8548X *NP*	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	5	..	10.59	11.68		Refresh Tears Plus	AG
8593G *NP*	Eye drops 10 mg per mL (1%), 15 mL	‡1	5	..	10.59	11.68		Refresh Liquigel	AG
	CARMELLOSE SODIUM **Restricted benefit** For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. **Note** No applications for increased maximum quantities and/or repeats will be authorised.								
9211T	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	11	..	10.59	11.68		Refresh Tears Plus	AG
9212W	Eye drops 10 mg per mL (1%), 15 mL	‡1	11	..	10.59	11.68		Refresh Liquigel	AG

Sensory organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	CARMELLOSE SODIUM **Authority required (STREAMLINED)** ***1359*** Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
2324H *NP*	Eye drops 10 mg per mL (1%), single dose units 0.4 mL, 30	3	5	..	*36.06	35.40		Celluvisc	AG
2338C *NP*	Eye drops 5 mg per mL (0.5%), single dose units 0.4 mL, 30	3	5	..	*36.06	35.40		Cellufresh	AG
8823J *NP*	Eye drops 2.5 mg per mL (0.25%), single dose units 0.6 mL, 24	4	5	..	*40.42	35.40		TheraTears	CX
8824K *NP*	Ocular lubricating gel 10 mg per mL (1%), single dose units 0.6 mL, 28	3	5	..	*34.08	35.17		TheraTears	CX
	CARMELLOSE SODIUM with GLYCERIN **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome. **Note** The in-use shelf life of Optive is 6 months from the date of opening.								
9355J *NP*	Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL	‡1	3	..	10.59	11.68		Optive	AG
	CARMELLOSE SODIUM with GLYCERIN **Restricted benefit** For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. **Note** No applications for increased maximum quantities and/or repeats will be authorised. **Note** The in-use shelf life of Optive is 6 months from the date of opening.								
9356K	Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL	‡1	7	..	10.59	11.68		Optive	AG
	CARMELLOSE SODIUM with GLYCERIN **Authority required (STREAMLINED)** ***1359*** Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
9307W *NP*	Eye drops 5 mg-9 mg per mL (0.5%-0.9%), single dose units 0.4 mL, 30	3	5	..	*36.06	35.40		Optive	AG
	HYPROMELLOSE **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome.								
2956N *NP*	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	5	..	10.27	11.36		Methopt	QA
8287E *NP*	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	‡1	5	..	10.27	11.36	[a]	In a Wink Moisturising	NM
				[B]1.95	12.22	11.36	[a]	Genteal	NV
	HYPROMELLOSE **Restricted benefit** For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. **Note** No applications for increased maximum quantities and/or repeats will be authorised.								
9213X	Eye drops 3 mg per mL (0.3%), 15 mL (contains	‡1	11	..	10.27	11.36	[a]	In a Wink	NM

Sensory organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	sodium perborate as preservative)							Moisturising	
				[B]1.95	12.22	11.36	a	Genteal	NV
9214Y	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	11	..	10.27	11.36		Methopt	QA
	HYPROMELLOSE with CARBOMER 980								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
8564R *NP*	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	‡1	5	..	10.27	11.36	a	HPMC PAA	NM
				[B]1.95	12.22	11.36	a	Genteal gel	NV
	HYPROMELLOSE with CARBOMER 980								
	Restricted benefit								
	For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9215B	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	‡1	11	..	10.27	11.36	a	HPMC PAA	NM
				[B]1.95	12.22	11.36	a	Genteal gel	NV
	HYPROMELLOSE with DEXTRAN								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
1509K *NP*	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	‡1	5	..	10.49	11.58	a	Poly-Tears	IQ
				[B]1.77	12.26	11.58	a	Tears Naturale	AQ
	HYPROMELLOSE with DEXTRAN								
	Restricted benefit								
	For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9216C	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	‡1	11	..	10.49	11.58	a	Poly-Tears	IQ
				[B]1.77	12.26	11.58	a	Tears Naturale	AQ
	HYPROMELLOSE with DEXTRAN								
	Authority required (STREAMLINED)								
	1359								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
8299T *NP*	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28	3	5	..	*35.07	35.40		Bion Tears	AQ
	PARAFFIN								
1750D *NP*	Pack containing 2 tubes compound eye ointment 3.5 g	‡1	5	..	20.60	21.69		Poly Visc	IQ
							a	Ircal	PE
				[B]2.12	22.72	21.69	a	Lacri-Lube	AG
1754H *NP*	Compound eye ointment 3.5 g	2	5	..	*21.24	22.33	a	Poly Visc	IQ
				[B]2.18	*23.42	22.33	a	Duratears	AQ

Sensory organs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	PARAFFIN								
	Restricted benefit								
	For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9217D	Compound eye ointment 3.5 g	2	11	..	*21.24	22.33	a	Poly Visc	IQ
				B2.18	*23.42	22.33	a	Duratears	AQ
9218E	Pack containing 2 tubes compound eye ointment 3.5 g	‡1	11	..	20.60	21.69		Poly Visc	IQ
							a	Ircal	PE
				B2.12	22.72	21.69	a	Lacri-Lube	AG
	POLYETHYLENE GLYCOL 400								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
	Note								
	The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening.								
9491M *NP*	Eye drops 2.5 mg per mL (0.25%), 15 mL	‡1	5	..	10.59	11.68		Blink Intensive Tears	AO
	POLYETHYLENE GLYCOL 400								
	Restricted benefit								
	For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
	Note								
	The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening.								
9492N	Eye drops 2.5 mg per mL (0.25%), 15 mL	‡1	11	..	10.59	11.68		Blink Intensive Tears	AO
	POLYETHYLENE GLYCOL 400								
	Authority required (STREAMLINED)								
	1359								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
9493P *NP*	Eye drops 2.5 mg per mL (0.25%), single dose units 0.4 mL, 20	5	5	..	*39.37	35.40		Blink Intensive Tears	AO
	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
8676P *NP*	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL	‡1	5	..	10.59	11.68		Systane	AQ
	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
	Restricted benefit								
	For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
9219F	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL	‡1	11	..	10.59	11.68		Systane	AQ
	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
	Authority required (STREAMLINED)								
	1359								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
9170P *NP*	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28	2	5	..	*34.08	35.17		Systane	AQ
	POLYVINYL ALCOHOL								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
2681D *NP*	Eye drops 30 mg per mL (3%), 15 mL	‡1	5	..	10.27	11.36	a	PVA Forte	PE
				[B]5.59	15.86	11.36	a	Liquifilm Forte	AG
2682E *NP*	Eye drops 14 mg per mL (1.4%), 15 mL	‡1	5	..	10.27	11.36	a	PVA Tears	PE
				[B]1.60	11.87	11.36	a	Liquifilm Tears	AG
8831T *NP*	Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡1	5	..	10.27	11.36		Vistil	AE
8832W *NP*	Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡1	5	..	10.27	11.36		Vistil Forte	AE
	POLYVINYL ALCOHOL								
	Restricted benefit								
	For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	Note								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9220G	Eye drops 14 mg per mL (1.4%), 15 mL	‡1	11	..	10.27	11.36	a	PVA Tears	PE
				[B]1.60	11.87	11.36	a	Liquifilm Tears	AG
9221H	Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡1	11	..	10.27	11.36		Vistil	AE
9222J	Eye drops 30 mg per mL (3%), 15 mL	‡1	11	..	10.27	11.36	a	PVA Forte	PE
				[B]5.59	15.86	11.36	a	Liquifilm Forte	AG
9223K	Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡1	11	..	10.27	11.36		Vistil Forte	AE
	SOY LECITHIN								
	Authority required (STREAMLINED)								
	1359								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
9448G *NP*	Eye spray 10 mg per mL (1%), 10 mL	2	5	..	*36.06	35.40		tearsagain	RB

Otologicals

Antiinfectives

Antiinfectives

	CHLORAMPHENICOL								
1172Q *NP*	Ear drops (aqueous) 5 mg per mL (0.5%), 5 mL	‡1	2	..	11.05	12.14		Chloromycetin	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	CIPROFLOXACIN								
	Authority required								
	Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older;								
	Treatment of chronic suppurative otitis media in a patient less than 18 years of age with perforation of the tympanic membrane;								
	Treatment of chronic suppurative otitis media in a patient less than 18 years of age with a grommet in situ.								
2480M *NP*	Ear drops 3 mg per mL (0.3%), 5 mL	‡1	1	..	19.28	20.37		Ciloxan	AQ
	NEOMYCIN UNDECENOATE with BACITRACIN ZINC								
2296W *NP*	Ear ointment 12 mg (3.5 mg base)-400 units per g, 10 g	‡1	..	..	8.66	9.75		Nemdyn	HA

Corticosteroids and antiinfectives in combination
Corticosteroids and antiinfectives in combination

	DEXAMETHASONE with FRAMYCETIN SULFATE and GRAMICIDIN								
2781J *NP*	Ear drops 500 micrograms-5 mg-50 micrograms per mL, 8 mL	‡1	2	..	9.39	10.48	a	Otodex	AV
				[B]1.91	11.30	10.48	a	Sofradex	SW
	TRIAMCINOLONE ACETONIDE with NEOMYCIN SULFATE, GRAMICIDIN and NYSTATIN								
2971J *NP*	Ear drops 1 mg-2.5 mg (base)- 250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 7.5 mL	‡1	2	..	11.09	12.18	a	Otocomb Otic	FM
				[B]1.95	13.04	12.18	a	Kenacomb Otic	QA
2974M *NP*	Ear ointment 1 mg-2.5 mg (base)-250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 5 g	‡1	2	..	8.18	9.27	a	Otocomb Otic	FM
				[B]1.95	10.13	9.27	a	Kenacomb Otic	QA

Ophthalmological and otological preparations

Antiinfectives
Antiinfectives

	FRAMYCETIN SULFATE								
1440T *NP,MW*	Eye and ear drops 5 mg per mL (0.5%), 8 mL	‡1	2	..	10.11	11.20		Soframycin	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Various

Allergens

Allergens

Allergen extracts

INSECT ALLERGEN EXTRACT—HONEY BEE VENOM

2886X	Injection set containing 550 micrograms	1	..	..	238.38	35.40	Albey Bee Venom	HL

INSECT ALLERGEN EXTRACT—PAPER WASP VENOM

Note

Paper wasp venom is not European wasp venom.

2918N	Injection set containing 550 micrograms	1	..	..	238.38	35.40	Albey Paper Wasp Venom	HL

INSECT ALLERGEN EXTRACT—YELLOW JACKET VENOM

2883R	Injection set containing 550 micrograms	1	..	..	238.38	35.40	Albey Yellow Jacket Venom	HL

All other therapeutic products

All other therapeutic products

Antidotes

NALOXONE HYDROCHLORIDE

1753G *NP*	Injection 2 mg in 5 mL	1	..	..	43.49	35.40	Naloxone Min-I-Jet	CS

Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority required (STREAMLINED)

3546

Maintenance therapy, following initiation and stabilisation of treatment with lanthanum carbonate, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy;

3547

Maintenance therapy, following initiation and stabilisation of treatment with lanthanum carbonate, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.

Note

Not to be used in combination with sevelamer.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9403X *NP*	Tablet, chewable, 500 mg (as carbonate hydrate)	90	5	..	305.87	35.40	Fosrenol	ZI
9404Y *NP*	Tablet, chewable, 750 mg (as carbonate hydrate)	90	5	..	449.42	35.40	Fosrenol	ZI
9405B *NP*	Tablet, chewable, 1000 mg (as carbonate hydrate)	90	5	..	504.03	35.40	Fosrenol	ZI

SEVELAMER HYDROCHLORIDE

Authority required (STREAMLINED)

3548

Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	3549								
	Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.								
	Note								
	Not to be used in combination with lanthanum.								
	Note								
	Shared Care Model:								
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2142R *NP*	Tablet 800 mg	180	5	..	357.73	35.40		Renagel	GZ

Detoxifying agents for antineoplastic treatment

	CALCIUM FOLINATE								
8740B	Injection equivalent to 50 mg folinic acid in 5 mL	5	5	..	*146.07	35.40	a	Leucovorin Calcium (Hospira Pty Limited)	HH
				..	146.10	35.40	a	Calcium Folinate Ebewe	SZ
				..	*147.04	35.40	a	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
8812T	Injection equivalent to 100 mg folinic acid in 10 mL	10	1	..	*258.72	35.40	a	Calcium Folinate Ebewe	SZ
				..	258.78	35.40	a	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
8969C	Injection equivalent to 1000 mg folinic acid in 100 mL	1	1	..	258.72	35.40		Calcium Folinate Ebewe	SZ
9041W	Injection equivalent to 300 mg folinic acid in 30 mL	4	1	..	*298.50	35.40	a	Calcium Folinate Ebewe	SZ
							a	Leucovorin Calcium (Hospira Pty Limited)	HH

	CALCIUM FOLINATE								
	Restricted benefit								
	Antidote to folic acid antagonists.								
2308L	Tablet equivalent to 15 mg folinic acid	10	..	..	96.31	35.40		Leucovorin Calcium (Hospira Pty Limited)	HH
	MESNA								
	Restricted benefit								
	Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide.								
8078E	Solution for I.V. injection 400 mg in 4 mL	15	5	..	103.28	35.40		Uromitexan	BX
8079F	Solution for I.V. injection 1 g in 10 mL	15	5	..	223.81	35.40		Uromitexan	BX

Drugs for treatment of hypercalcemia

SODIUM ACID PHOSPHATE

Authority required (STREAMLINED)

1099

Familial hypophosphataemia;

1157

Hypercalcaemia;

1167

Hypophosphataemic rickets;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	1467 Vitamin D-resistant rickets.							
2946C *NP*	Compound effervescent tablet containing elemental phosphorus 500 mg, sodium 469 mg (20.4 mmol), potassium 123 mg (3.1 mmol)	100	5	..	81.63	35.40	Phosphate Sandoz	NV

Other therapeutic products

POLY-L-LACTIC ACID

Note

Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9475Q	Powder for injection 150 mg	2	4	..	*446.46	35.40	Sculptra	SW

POLY-L-LACTIC ACID

Note

Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Maintenance PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

9476R	Powder for injection 150 mg	2	..	..	*446.46	35.40	Sculptra	SW

Diagnostic agents

Urine tests

GLUCOSE and KETONE INDICATOR—URINE

3106L *NP*	Test strips, 50	2	2	..	*17.30	18.39	Keto-Diabur- Test 5000	RD
3107M *NP*	Test strips, 50	2	2	..	*17.42	18.51	Keto-Diastix	BN

GLUCOSE and KETONE INDICATOR—URINE

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9254C	Test strips, 50	2	4	..	*17.30	18.39	Keto-Diabur- Test 5000	RD
9255D	Test strips, 50	2	4	..	*17.42	18.51	Keto-Diastix	BN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	GLUCOSE INDICATOR—URINE							
3104J *NP*	Test strips, 50	2	2	..	*19.82	20.91	Diastix	BN

GLUCOSE INDICATOR—URINE

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9253B	Test strips, 50	2	4	..	*19.82	20.91	Diastix	BN

Other diagnostic agents
Tests for diabetes

	GLUCOSE INDICATOR—BLOOD							
1503D *NP*	Test strips, 100	‡1	5	..	53.16	35.40	Contour	IK
2263D *NP*	Test strips, 50	2	5	..	*53.18	35.40	Optium Omega	MS
2860M *NP*	Test strips, 50	2	5	..	*53.18	35.40	Betachek G5	NA
2890D *NP*	Test strips, 50	2	5	..	*53.18	35.40	Betachek	NA
2914J *NP*	Test strips, 50	2	5	..	*45.90	35.40	Glucoflex-R	NA
2979T *NP*	Test strips, 100	‡1	5	..	53.16	35.40	Accu-Chek Performa	RD
3406G *NP*	Test strips, 50	2	5	..	*53.18	35.40	CareSens N	LB
3411M *NP*	Test strips, 100	‡1	5	..	53.16	35.40	Accu-Chek Advantage/Sens or Comfort	RD
3441D *NP*	Test strips, 50	2	5	..	*53.18	35.40	OneTouch Verio	JJ
5043K *NP*	Test strips, 50	2	5	..	*53.18	35.40	Accu-Chek Aviva	RD
5266E *NP*	Test strips, 50	2	5	..	*53.18	35.40	TRUEresult	NX
5267F *NP*	Test strips, 50	2	5	..	*53.18	35.40	TRUEbalance	NX
8190C *NP*	Test strips, 100	‡1	5	..	53.16	35.40	Accu-Chek Active	RD
8522M *NP*	Test strips, 100	‡1	5	..	53.16	35.40	FreeStyle Optium	MS
8723D *NP*	Test strips, 50	2	5	..	*53.18	35.40	Omnitest EZ	BR
8739Y *NP*	Test strips, 50	2	5	..	*53.18	35.40	Accu-Chek Go	RD
8749L *NP*	Test strips, 50	2	5	..	*53.18	35.40	GlucoOz	OZ
8759B *NP*	Test strips, 50	2	5	..	*53.18	35.40	CareSens	LB
8795X *NP*	Test strips, 50	2	5	..	*53.18	35.40	SensoCard	PX
8806L *NP*	Test strips, 51	2	5	..	*53.18	35.40	Accu-Chek Integra	RD
8825L *NP*	Test strips, 50	2	5	..	*53.18	35.40	TrueTrack	NX
9013J *NP*	Test strips, 50	2	5	..	*53.18	35.40	Glucocard 01 Sensor	OZ
9154T *NP*	Test strips, 100	‡1	5	..	53.16	35.40	FreeStyle Lite	MS
9193W *NP*	Test strips, 25	4	5	..	*53.18	35.40	On-Call Plus	PZ

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
9298J *NP*	Test strips, 50	2	5	..	*53.18	35.40	Bionime Rightest	QB
9324R *NP*	Test strips, 50	2	5	..	*53.18	35.40	AgaMatrix Jazz	HE
9471L *NP*	Test strips, 50	2	5	..	*53.18	35.40	MyGlucoHealth	EH
9485F *NP*	Test strips, 50	2	5	..	*53.18	35.40	Lifeline Attest	OI

GLUCOSE INDICATOR—BLOOD

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

1518X	Test strips, 100	‡1	11	..	53.16	35.40	Contour	IK
3407H	Test strips, 50	2	11	..	*53.18	35.40	CareSens N	LB
3412N	Test strips, 100	‡1	11	..	53.16	35.40	Accu-Chek Advantage/Sens or Comfort	RD
3442E	Test strips, 50	2	11	..	*53.18	35.40	OneTouch Verio	JJ
5053Y	Test strips, 50	2	11	..	*53.18	35.40	Accu-Chek Aviva	RD
5268G	Test strips, 50	2	11	..	*53.18	35.40	TRUEresult	NX
5269H	Test strips, 50	2	11	..	*53.18	35.40	TRUEbalance	NX
9256E	Test strips, 25	4	11	..	*53.18	35.40	On-Call Plus	PZ
9257F	Test strips, 100	‡1	11	..	53.16	35.40	Accu-Chek Performa	RD
9261K	Test strips, 50	2	11	..	*53.18	35.40	Glucocard 01 Sensor	OZ
9263M	Test strips, 50	2	11	..	*53.18	35.40	GlucoOz	OZ
9265P	Test strips, 50	2	11	..	*53.18	35.40	Omnitest EZ	BR
9267R	Test strips, 50	2	11	..	*53.18	35.40	Optium Omega	MS
9268T	Test strips, 50	2	11	..	*53.18	35.40	TrueTrack	NX
9269W	Test strips, 100	‡1	11	..	53.16	35.40	FreeStyle Lite	MS
9270X	Test strips, 100	‡1	11	..	53.16	35.40	FreeStyle Optium	MS
9273C	Test strips, 100	‡1	11	..	53.16	35.40	Accu-Chek Active	RD
9274D	Test strips, 50	2	11	..	*53.18	35.40	Accu-Chek Go	RD
9275E	Test strips, 51	2	11	..	*53.18	35.40	Accu-Chek Integra	RD
9276F	Test strips, 50	2	11	..	*53.18	35.40	Betachek	NA
9277G	Test strips, 50	2	11	..	*53.18	35.40	Betachek G5	NA
9278H	Test strips, 50	2	11	..	*53.18	35.40	CareSens	LB
9279J	Test strips, 50	2	11	..	*45.90	35.40	Glucoflex-R	NA
9281L	Test strips, 50	2	11	..	*53.18	35.40	SensoCard	PX
9297H	Test strips, 50	2	11	..	*53.18	35.40	Bionime Rightest	QB
9325T	Test strips, 50	2	11	..	*53.18	35.40	AgaMatrix Jazz	HE
9472M	Test strips, 50	2	11	..	*53.18	35.40	MyGlucoHealth	EH
9486G	Test strips, 50	2	11	..	*53.18	35.40	Lifeline Attest	OI

GLUCOSE INDICATOR—BLOOD

Restricted benefit

For use in patients on insulin therapy.

9300L *NP*	Test strips, 100	‡1	5	..	53.16	35.40	Accu-Chek Mobile	RD

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

GLUCOSE INDICATOR—BLOOD

Restricted benefit

For use in patients on insulin therapy who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9301M	Test strips, 100	‡1	11	..	53.16	35.40	Accu-Chek Mobile	RD

General nutrients

Other nutrients

TRIGLYCERIDES, MEDIUM CHAIN

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Chylous ascites;

Chylothorax;

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;

Hyperlipoproteinaemia type 1;

Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet;

Long chain fatty acid oxidation disorders.

3128P *NP*	Oil 500 mL	2	5	..	*52.38	35.40	MCT Oil	SB
9327X *NP*	Emulsion 250 mL	8	5	..	*214.42	35.40	Liquigen	SB

Fat/carbohydrates/proteins/minerals/vitamins, combinations

AMINO ACIDS—SYNTHETIC, FORMULA

Authority required

Initial treatment for up to 3 months, by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who requires an amino acid based formula as a component of a dietary elimination programme. Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority.

Authority required

Continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who has responded to an initial course of PBS-subsidised treatment. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

Note

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

2250K *NP*	Compound powder 400 g	12	5	..	*531.66	35.40	EleCare	AB

AMINO ACIDS—SYNTHETIC, FORMULA

Authority required

Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application; Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
1180D *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	Neocate Advance Vanilla	SB
2244D *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	Neocate Advance Tropical Flavour	SB
8574G *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	EleCare	AB
8754R *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	Neocate Advance	SB
	AMINO ACIDS—SYNTHETIC, FORMULA **Authority required** Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application; Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application; Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application; Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application; Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed; Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition. **Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.							
1192R *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	Neocate Advance Vanilla	SB
2553J *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	Neocate Advance Tropical Flavour	SB
8575H *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	EleCare	AB
8755T *NP*	Compound powder 400 g	8	5	..	*361.14	35.40	Neocate Advance	SB
	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS **Authority required** Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application; Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
2246F *NP*	Compound powder 400 g	8	5	..	*367.86	35.40	Neocate LCP	SB
9339M *NP*	Compound powder 400 g	8	5	..	*367.86	35.40	EleCare LCP	AB

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS							
	Authority required							
	Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application;							
	Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application;							
	Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;							
	Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;							
	Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.							
	Note							
	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.							
2560R *NP*	Compound powder 400 g	8	5	..	*367.86	35.40	Neocate LCP	SB
9340N *NP*	Compound powder 400 g	8	5	..	*367.86	35.40	EleCare LCP	AB
	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN TRIGLYCERIDES							
	Authority required							
	Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application;							
	Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application.							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5466Q *NP*	Compound powder 400 g	8	5	..	*367.86	35.40	Neocate Gold	SB
	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN TRIGLYCERIDES							
	Authority required							
	Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application;							
	Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application;							
	Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;							
	Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;							
	Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.							
	Note							
	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.							
5467R *NP*	Compound powder 400 g	8	5	..	*367.86	35.40	Neocate Gold	SB

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	PROTEIN HYDROLYSATE FORMULA with MEDIUM CHAIN TRIGLYCERIDES							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Authority required							
	Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application.							
	Authority required							
	Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application.							
	Authority required							
	Biliary atresia;							
	Chronic liver failure with fat malabsorption;							
	Chylous ascites;							
	Chylothorax;							
	Cystic fibrosis;							
	Enterokinase deficiency;							
	Proven fat malabsorption;							
	Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application;							
	Severe intestinal malabsorption including short bowel syndrome.							
2676W *NP*	Compound powder 400 g	8	5	..	*171.94	35.40	Alfaré	NT

PROTEIN HYDROLYSATE FORMULA with MEDIUM CHAIN TRIGLYCERIDES

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application;

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application;

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application.

Authority required

Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application;

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application;

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application.

Authority required

Biliary atresia;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Chronic liver failure with fat malabsorption; Chylous ascites; Cystic fibrosis; Enterokinase deficiency; Proven fat malabsorption; Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application; Severe intestinal malabsorption including short bowel syndrome.							
8259Q *NP*	Compound powder 450 g	8	5	..	*109.86	35.40	Karicare Aptamil Pepti-Junior Gold	NU

TRIGLYCERIDES—MEDIUM CHAIN, FORMULA

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Restricted benefit

Chylous ascites;

Chylothorax;

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;

Hyperlipoproteinaemia type 1;

Long chain fatty acid oxidation disorders.

Note

Monogen is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

8478F *NP*	Compound powder 400 g	8	5	..	*421.30	35.40	Monogen	SB

TRIGLYCERIDES—MEDIUM CHAIN, FORMULA

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Restricted benefit

Chylous ascites;

Chylothorax;

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.

Note

Caprilon is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet, long chain fatty acid oxidation disorders or hyperlipoproteinaemia type 1.

8629E *NP*	Compound powder 420 g	8	5	..	*467.46	35.40	Caprilon	SB

Carbohydrates

AMYLOPECTIN, MODIFIED LONG CHAIN

Restricted benefit

Glycogen storage disease.

9386B *NP*	Sachets 60 g, 30	4	5	..	*752.30	35.40	Glycosade	VF

Milk substitutes

MILK POWDER—LACTOSE FREE FORMULA

Authority required

Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application.

Note

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
2350Q *NP*	Lactose-predigested powder infant formula 900 g	5	..	..	*88.92	35.40	Karicare Aptamil De-Lact	NU
8282X *NP*	Infant formula powder 900 g	5	..	..	*112.87	35.40	S-26 LF	PF

MILK POWDER—LACTOSE FREE FORMULA

Authority required

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

2349P *NP*	Lactose-predigested powder infant formula 900 g	5	5	..	*88.92	35.40	Karicare Aptamil De-Lact	NU
8283Y *NP*	Infant formula powder 900 g	5	5	..	*112.87	35.40	S-26 LF	PF

MILK POWDER—LACTOSE MODIFIED

Authority required

Acute lactose intolerance in children aged 1 year and over. The date of birth of the patient must be included in the authority application.

Note

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

2358D *NP*	Lactose-predigested powder 900 g	3	1	..	*72.81	35.40	Digestelact	SJ

MILK POWDER—LACTOSE MODIFIED

Authority required

Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

2357C *NP*	Lactose-predigested powder 900 g	3	10	..	*72.81	35.40	Digestelact	SJ

MILK POWDER—SYNTHETIC

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Hypercalcaemia in children under the age of 4 years.

3092R *NP*	Low calcium compound powder 400 g	8	5	..	*381.38	35.40	Locasol	SB

Other combinations of nutrients

AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS, and TRACE ELEMENTS, without METHIONINE and supplemented with DOCOSAHEXANOIC ACID

Restricted benefit

Pyridoxine non-responsive homocystinuria.

3417W *NP*	Oral liquid 125 mL, 36	4	5	..	*2507.98	35.40	HCU Anamix junior LQ	SB

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS without PHENYLALANINE and TYROSINE, and supplemented with DOCOSAHEXANOIC ACID **Restricted benefit** Tyrosinaemia.							
9330C *NP*	Oral liquid 125 mL, 36	4	5	..	*2507.98	35.40	TYR Anamix junior LQ	SB
	AMINO ACID FORMULA without PHENYLALANINE **Restricted benefit** Phenylketonuria.							
2347M *NP*	Sachets containing powder 20 g, 30	7	5	..	*1462.91	35.40	Phlexy-10 Drink Mix	SB
8554F *NP*	Capsules 500 mg, 200	16	5	..	*1276.34	35.40	Phlexy-10	SB
8678R *NP*	Tablets 1 g, 75	24	5	..	*1426.98	35.40	Phlexy-10	SB
	AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE **Restricted benefit** Phenylketonuria.							
8479G *NP*	Infant formula, powder 400 g	8	5	..	*703.62	35.40	PKU Anamix infant	SB
	AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN **Restricted benefit** A child aged from 6 months up to 10 years with proven glutaric aciduria type 1.							
9438R *NP*	Sachets 24 g, 30	4	5	..	*2114.38	35.40	GA gel	VF
	AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN **Restricted benefit** An infant or young child with proven glutaric aciduria type 1.							
2650L *NP*	Infant formula, powder 400 g	8	5	..	*769.30	35.40	GA1 Anamix infant	SB
	AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN **Restricted benefit** A child aged less than 9 years with proven glutaric aciduria type 1.							
2646G *NP*	Powder 500 g	8	5	..	*1784.74	35.40	XLYS, LOW TRY Maxamaid	SB
	AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN **Restricted benefit** A patient aged 3 years or older with proven glutaric aciduria type 1.							
5484P *NP*	Sachets 25 g, 30	4	5	..	*3154.42	35.40	GA express	VF
	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE **Restricted benefit** For infants and very young children with pyridoxine non-responsive homocystinuria.							
8417B *NP*	Infant formula, powder 400 g	8	5	..	*769.30	35.40	HCU Anamix infant	SB

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE							
	Restricted benefit							
	Pyridoxine non-responsive homocystinuria.							
8328H	Powder 500 g	8	5	..	*1784.74	35.40	XMET Maxamaid	SB
NP								
8416Y	Powder 500 g	8	5	..	*2704.74	35.40	XMET Maxamum	SB
NP								
8677Q	Sachets 24 g, 30	4	5	..	*2114.38	35.40	HCU gel	VF
NP								
8744F	Sachets 25 g, 30	4	5	..	*3098.38	35.40	HCU express	VF
NP								
9133Q	Oral liquid 130 mL, 30	4	5	..	*3098.38	35.40	HCU Cooler	VF
NP								
	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE							
	Restricted benefit							
	Methylmalonic acidaemia;							
	Propionic acidaemia.							
3443F	Sachets 25 g, 30	4	5	..	*3098.38	35.40	MMA/PA express	VF
NP								
3444G	Sachets 24 g, 30	4	5	..	*2114.38	35.40	MMA/PA gel	VF
NP								
8058D	Infant formula, powder 400 g	8	5	..	*769.30	35.40	MMA/PA Anamix infant	SB
NP								
8059E	Powder 500 g	8	5	..	*1784.74	35.40	XMTVI Maxamaid	SB
NP								
8061G	Powder 500 g	8	5	..	*2704.74	35.40	XMTVI Maxamum	SB
NP								
	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE							
	Restricted benefit							
	Phenylketonuria.							
1411G	Sachets 18.2 g, 60	3	5	..	*1640.07	35.40	add-ins	SB
NP								
2382J	Oral liquid 87 mL, 30	4	5	..	*1034.78	35.40	PKU Cooler 10	VF
NP								
2474F	Oral liquid 174 mL, 30	4	5	..	*2054.02	35.40	PKU Cooler 20	VF
NP								
2738D	Powder 500 g	8	5	..	*884.02	35.40	XP Maxamaid	SB
NP								
2739E	Powder 500 g	8	5	..	*1352.42	35.40	XP Maxamum	SB
NP								
5483N	Oral gel 85 g, 30	4	5	..	*1058.62	35.40	PKU squeezie	VF
NP								
8545R	Powder 400 g	8	5	..	*848.58	35.40	Phenex-2	AB
NP								
8555G	Sachets 24 g, 30	4	5	..	*1058.62	35.40	PKU gel	VF
NP								
8591E	Sachets 25 g, 30	4	5	..	*1549.14	35.40	PKU-Express	VF
NP								
8613H	Sachets 29 g, 30	4	5	..	*892.10	35.40	PKU Anamix Junior	SB
NP								
8727H	Sachets 50 g, 30	3	5	..	*1512.06	35.40	XP Maxamum	SB
NP								
8746H	Oral liquid 250 mL	90	5	..	*1313.27	35.40	Easiphen	SB
NP								
8804J	Sachets 27.8 g, 30	3	5	..	*1549.44	35.40	Lophlex	SB
NP								
8846N	Oral liquid 130 mL, 30	4	5	..	*1548.34	35.40	PKU Cooler 15	VF
NP								
9021T	Oral liquid 125 mL, 30	3	5	..	*1549.44	35.40	PKU Lophlex LQ 20	SB
NP								
9396M	Oral liquid 125 mL, 36	4	5	..	*1269.86	35.40	PKU Anamix Junior LQ	SB
NP								
9397N	Oral liquid 62.5 mL, 60	2	5	..	*1059.36	35.40	PKU Lophlex LQ 10	SB

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
NP								
	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE							
	Restricted benefit							
	Tyrosinaemia.							
3078B	Powder 500 g	8	5	..	*2704.74	35.40	XPhen, Tyr Maxamum	SB
NP								
8445L	Infant formula, powder 400 g	8	5	..	*769.30	35.40	TYR Anamix infant	SB
NP								
8446M	Powder 500 g	8	5	..	*1784.74	35.40	XPhen, Tyr Maxamaid	SB
NP								
8631G	Sachets 24 g, 30	4	5	..	*2114.38	35.40	TYR gel	VF
NP								
8667E	Sachets 25 g, 30	4	5	..	*3098.38	35.40	TYR Express	VF
NP								
9132P	Oral liquid 130 mL, 30	4	5	..	*3098.38	35.40	TYR Cooler	VF
NP								
9395L	Sachets 29 g, 30	4	5	..	*1800.46	35.40	TYR Anamix Junior	SB
NP								
	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE							
	Restricted benefit							
	Maple syrup urine disease.							
2375B	Oral liquid 130 mL, 30	4	5	..	*3098.38	35.40	MSUD Cooler	VF
NP								
2380G	Infant formula, powder 400 g	8	5	..	*769.30	35.40	MSUD Anamix infant	SB
NP								
8057C	Powder 500 g	8	5	..	*2704.74	35.40	MSUD Maxamum	SB
NP								
8260R	Powder 500 g	8	5	..	*1784.74	35.40	MSUD Maxamaid	SB
NP								
8310J	Powder 500 g	4	5	..	*2671.98	35.40	MSUD AID III	SB
NP								
8592F	Sachets 24 g, 30	4	5	..	*2114.38	35.40	MSUD gel	VF
NP								
8632H	Sachets 25 g, 30	4	5	..	*3098.38	35.40	MSUD Express	VF
NP								
8745G	Sachets 29 g, 30	4	5	..	*1800.46	35.40	MSUD Anamix Junior	SB
NP								
	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE with FAT, CARBOHYDRATE and TRACE ELEMENTS and supplemented with DOCOSAHEXANOIC ACID							
	Restricted benefit							
	Maple syrup urine disease.							
9499Y	Oral liquid 125 mL, 36	4	5	..	*2507.98	35.40	MSUD Anamix Junior LQ	SB
NP								
	ARGININE with CARBOHYDRATE							
	Restricted benefit							
	Urea cycle disorders.							
	Note							
	Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.							
5482M	Sachets 4 g containing 2 g arginine, 30	4	5	..	*770.82	35.40	Arginine 2000 Amino Acid Supplement	VF
NP								
9437Q	Sachets 4 g containing 500 mg arginine, 30	4	5	..	*516.02	35.40	Arginine Amino Acid Supplement	VF
NP								
	CARBOHYDRATE, FAT, VITAMINS, MINERALS and TRACE ELEMENTS							
	Restricted benefit							
	Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.							

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
8369L *NP*	Powder 400 g	8	5	..	*318.18	35.40	Energivit	SB
	CITRULLINE with CARBOHYDRATE **Restricted benefit** Urea cycle disorders in order to prevent low plasma arginine or citrulline levels. **Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.							
5481L *NP*	Sachets 4 g containing 1 g citrulline, 30	4	5	..	*516.02	35.40	Citrulline 1000 Amino Acid Supplement	VF
	CYSTINE with CARBOHYDRATE **Restricted benefit** Pyridoxine non-responsive homocystinuria.							
9164H *NP*	Sachets 4 g containing 500 mg cystine, 30	4	5	..	*516.02	35.40	Cystine Amino Acid Supplement	VF
	ESSENTIAL AMINO ACIDS FORMULA **Restricted benefit** Gyrate atrophy of the choroid and retina; Urea cycle disorders.							
9329B *NP*	Powder 200 g	6	5	..	*1200.54	35.40	Essential Amino Acid Mix	SB
	ESSENTIAL AMINO ACIDS FORMULA with MINERALS and VITAMIN C **Restricted benefit** Gyrate atrophy of the choroid and retina; Urea cycle disorders.							
2027Q *NP*	Powder 400 g	5	5	..	*634.17	35.40	Dialamine	SB
	ESSENTIAL AMINO ACIDS FORMULA with VITAMINS and MINERALS **Restricted benefit** Gyrate atrophy of the choroid and retina; Urea cycle disorders.							
9385Y *NP*	Sachets 12.5 g, 50	4	5	..	*1516.50	35.40	EAA Supplement	VF
	HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and low in PROTEIN and CARBOHYDRATE **Restricted benefit** Patients with intractable seizures requiring treatment with a ketogenic diet; Glucose transport protein defects; Pyruvate dehydrogenase deficiency. **Note** KetoCal should only be used under strict supervision of a dietician, together with a metabolic physician and/or neurologist. **Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.							
9446E *NP*	Powder 300 g	24	5	..	*1037.46	35.40	KetoCal	SB
	ISOLEUCINE with CARBOHYDRATE **Restricted benefit** Maple syrup urine disease.							
9134R	Sachets 4 g containing 50 mg isoleucine, 30	4	5	..	*516.02	35.40	Isoleucine Amino	VF

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
NP							Acid Supplement	
9436P *NP*	Sachets 4 g containing 1 g isoleucine, 30	4	5	..	*566.98	35.40	Isoleucine 1000 Amino Acid Supplement	VF

MILK PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE

Restricted benefit

Patients with intractable seizures requiring treatment with a ketogenic diet;

Glucose transport protein defects;

Pyruvate dehydrogenase deficiency;

Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance.

8630F *NP*	Powder 225 g	24	5	..	*648.42	35.40	Carbohydrate Free Mixture	SB

PHENYLALANINE with CARBOHYDRATE

Restricted benefit

Tyrosinaemia.

9384X *NP*	Sachets 4 g containing 50 mg phenylalanine, 30	4	5	..	*516.02	35.40	Phenylalanine Amino Acid Supplement	VF

SOY PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE

Restricted benefit

Patients with intractable seizures requiring treatment with a ketogenic diet;

Glucose transport protein defects;

Pyruvate dehydrogenase deficiency;

Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance.

8577K *NP*	Liquid 384 mL	120	5	..	*670.02	35.40	RCF	AB

TRIGLYCERIDES, LONG CHAIN with GLUCOSE POLYMER

Restricted benefit

Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.

9308X *NP*	Oral liquid 250 mL, 18	6	5	..	*339.78	35.40	ProZero	VF
9309Y *NP*	Oral liquid 1 L, 6	4	5	..	*304.02	35.40	ProZero	VF

TRIGLYCERIDES, MEDIUM CHAIN and LONG CHAIN with GLUCOSE POLYMER

Restricted benefit

Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.

3136C *NP*	Compound powder 400 g	8	5	..	*295.54	35.40	Duocal	SB

TRIGLYCERIDES—MEDIUM CHAIN, FORMULA

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Chylous ascites;

Chylothorax;

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;

Hyperlipoproteinaemia type 1;

Long chain fatty acid oxidation disorders.

Note

MCT Pro-Cal is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
9383W *NP*	Sachets 16 g, 30	4	5	..	*253.62	35.40	MCT Pro-Cal	VF
	TYROSINE with CARBOHYDRATE **Restricted benefit** Phenylketonuria.							
9165J *NP*	Sachets 4 g containing 1 g tyrosine, 30	4	5	..	*516.02	35.40	Tyrosine Amino Acid Supplement	VF
	VALINE with CARBOHYDRATE **Restricted benefit** Maple syrup urine disease.							
9135T *NP*	Sachets 4 g containing 50 mg valine, 30	4	5	..	*516.02	35.40	Valine Amino Acid Supplement	VF
9434M *NP*	Sachets 4 g containing 1 g valine, 30	4	5	..	*566.98	35.40	Valine 1000 Amino Acid Supplement	VF
	VITAMINS, MINERALS and TRACE ELEMENTS with CARBOHYDRATE **Authority required** Infants and children whose vitamin and mineral intake is insufficient due to a specific diagnosis requiring a highly restrictive therapeutic diet, and whose vitamin, mineral and trace element needs cannot be adequately met with other proprietary vitamin and mineral preparations. **Note** Paediatric Seravit should only be used under strict supervision of a dietitian and a paediatrician.							
9328Y *NP*	Powder 200 g	6	5	..	*390.42	35.40	Paediatric Seravit	SB
	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE **Authority required** Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet.							
9382T *NP*	Sachets 100 g, 10	9	5	..	*1485.57	35.40	RenaStart	VF
	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE **Authority required** Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet.							
8587Y *NP*	Powder 400 g	16	5	..	*1065.94	35.40	Kindergen	SB

All other non-therapeutic products

All other non-therapeutic products
Solvents and diluting agents, incl. irrigating solutions

	SODIUM CHLORIDE							
2026P *NP*	Injection 9 mg per mL (0.9%), 10 mL	5	1	..	8.12	9.21	Pfizer Australia Pty Ltd	PF

Pharmaceutical Benefits for Palliative Care

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Alimentary tract and metabolism

Stomatological preparations

Stomatological preparations

Other agents for local oral treatment

BENZYDAMINE HYDROCHLORIDE
Authority required (STREAMLINED)
3634
Initial supply, for up to 4 months, for a palliative care patient where a painful mouth is a problem.

5385K *NP*	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	‡1	3	..	22.26	23.35	Difflam	IA

BENZYDAMINE HYDROCHLORIDE
Authority required (STREAMLINED)
3635
Continuing supply for a palliative care patient where a painful mouth is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5386L *NP*	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	‡1	..	..	22.26	23.35	Difflam	IA

CARMELLOSE SODIUM
Authority required (STREAMLINED)
3636
Initial supply, for up to 4 months, for a palliative care patient where dry mouth is a symptom.

5333Q *NP*	Mouth spray 10 mg per mL, 25 mL	‡1	3	..	10.79	11.88	Aquae	VT
5334R *NP*	Mouth spray 10 mg per mL, 100 mL	‡1	3	..	12.46	13.55	Aquae	VT

CARMELLOSE SODIUM
Authority required (STREAMLINED)
3637
Continuing supply for a palliative care patient where dry mouth is a symptom.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5335T *NP*	Mouth spray 10 mg per mL, 25 mL	‡1	..	..	10.79	11.88	Aquae	VT
5336W *NP*	Mouth spray 10 mg per mL, 100 mL	‡1	..	..	12.46	13.55	Aquae	VT

HYPROMELLOSE
Authority required (STREAMLINED)
3636
Initial supply, for up to 4 months, for a palliative care patient where dry mouth is a symptom.

5421H *NP*	Oral gel 20 mg per g, 100 g	‡1	3	..	12.65	13.74	Aquae Gel	VT

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	HYPROMELLOSE **Authority required (STREAMLINED)** ***3637*** Continuing supply for a palliative care patient where dry mouth is a symptom. **Note** Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5422J *NP*	Oral gel 20 mg per g, 100 g	‡1	..	..	12.65	13.74		Aquae Gel	VT

Drugs for functional gastrointestinal disorders

Belladonna and derivatives, plain

Belladonna alkaloids semisynthetic, quaternary ammonium compounds

	HYOSCINE BUTYLBROMIDE **Authority required (STREAMLINED)** ***3638*** Initial supply, for up to 4 months, for a palliative care patient where colicky pain is a symptom.								
5317W *NP*	Injection 20 mg in 1 mL	30	3	..	*108.54	35.40		Buscopan	BY
	HYOSCINE BUTYLBROMIDE **Authority required (STREAMLINED)** ***3639*** Continuing supply for a palliative care patient where colicky pain is a symptom. **Note** Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5318X *NP*	Injection 20 mg in 1 mL	30	..	..	*108.54	35.40		Buscopan	BY

Laxatives

Laxatives

Contact laxatives

	BISACODYL **Authority required (STREAMLINED)** ***3642*** Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.								
5301B *NP*	Tablet 5 mg	200	3	..	14.11	15.20		Bisalax	AS
								Lax-Tab	AE
5303D *NP*	Suppositories 10 mg, 10	3	3	..	*20.94	22.03	[a]	Petrus Bisacodyl Suppositories	PP
				[B]1.50	*22.44	22.03	[a]	Dulcolax	BY
5304E *NP*	Suppositories 10 mg, 12	3	3	..	*18.33	19.42		Petrus Bisacodyl Suppositories	PP
	BISACODYL **Authority required (STREAMLINED)** ***3643*** Continuing supply for a palliative care patient where constipation is a problem.								

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5305F *NP*	Tablet 5 mg	200	..	..	14.11	15.20		Bisalax	AS
								Lax-Tab	AE
5307H *NP*	Suppositories 10 mg, 10	3	..	..	*20.94	22.03	a	Petrus Bisacodyl Suppositories	PP
				[B]1.50	*22.44	22.03	a	Dulcolax	BY
5308J *NP*	Suppositories 10 mg, 12	3	..	..	*18.33	19.42		Petrus Bisacodyl Suppositories	PP

Bulk producers

STERCULIA with FRANGULA BARK
Authority required (STREAMLINED)
3642
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.

5322D *NP*	Granules 620 mg-80 mg per g (62%-8%), 500 g	‡1	3	..	26.37	27.46		Normacol Plus	NE

STERCULIA with FRANGULA BARK
Authority required (STREAMLINED)
3643
Continuing supply for a palliative care patient where constipation is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5324F *NP*	Granules 620 mg-80 mg per g (62%-8%), 500 g	‡1	..	..	26.37	27.46		Normacol Plus	NE

Osmotically acting laxatives

LACTULOSE
Authority required (STREAMLINED)
3642
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.

5387M *NP*	Mixture 3.34 g per 5 mL, 500 mL	3	3	..	*23.19	24.28	a	Actilax	AF
							a	Genlac	QA
							a	GenRx Lactulose	GX
							a	Lac-Dol	GM
							a	Lactocur	SZ
				[B]3.60	*26.79	24.28	a	Duphalac	AB

LACTULOSE
Authority required (STREAMLINED)
3643
Continuing supply for a palliative care patient where constipation is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5388N *NP*	Mixture 3.34 g per 5 mL, 500 mL	3	..	..	*23.19	24.28	a	Actilax	AF
							a	Genlac	QA
							a	GenRx Lactulose	GX

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Lac-Dol	GM
							[a]	Lactocur	SZ
				[B]3.60	*26.79	24.28	[a]	Duphalac	AB

MACROGOL 3350
Authority required (STREAMLINED)
3642
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.

5389P *NP*	Sachets containing powder for solution 13.125 g with electrolytes, 30	2	3	..	*34.68	35.40		Movicol	NE
5426N *NP*	Powder for oral solution 510 g	2	3	..	*34.68	35.40	[a]	MediHealth ClearLax	ON
							[a]	OsmoLax	KY
							[a]	your pharmacy Clear Laxative	OY

MACROGOL 3350
Authority required (STREAMLINED)
3643
Continuing supply for a palliative care patient where constipation is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5390Q *NP*	Sachets containing powder for solution 13.125 g with electrolytes, 30	2	..	..	*34.68	35.40		Movicol	NE
5427P *NP*	Powder for oral solution 510 g	2	..	..	*34.68	35.40	[a]	MediHealth ClearLax	ON
							[a]	OsmoLax	KY
							[a]	your pharmacy Clear Laxative	OY

Enemas

BISACODYL
Authority required (STREAMLINED)
3642
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.

5302C *NP*	Enemas 10 mg in 5 mL, 25	‡1	3	..	37.94	35.40		Bisalax	AS

BISACODYL
Authority required (STREAMLINED)
3643
Continuing supply for a palliative care patient where constipation is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5306G *NP*	Enemas 10 mg in 5 mL, 25	‡1	..	..	37.94	35.40		Bisalax	AS

SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE
Authority required (STREAMLINED)
3642
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.

5331N *NP*	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2	3	..	*32.28	33.37	[a]	Micolette	AE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Microlax	JT

SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE
Authority required (STREAMLINED)
3643
Continuing supply for a palliative care patient where constipation is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5332P *NP*	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2	..	..	*32.28	33.37	[a]	Micolette	AE
							[a]	Microlax	JT

Peripheral opioid receptor antagonists

METHYLNALTREXONE
Authority required
Initial supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has failed to respond to laxatives.

Note
No applications for repeats will be authorised.

Note
Special Pricing Arrangements apply.

5423K *NP*	Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL	3	..	..	*130.59	35.40		Relistor	LM

METHYLNALTREXONE
Authority required
Continuing supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has demonstrated a response to methylnaltrexone.

Note
For first continuing supply, applications for increased repeats may be authorised.
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

Note
Special Pricing Arrangements apply.

5424L *NP*	Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL	7	..	..	287.84	35.40		Relistor	LM

Other laxatives

GLYCEROL
Authority required (STREAMLINED)
3642
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.

5311M *NP*	Suppositories 700 mg (for infants), 12	3	3	..	*19.47	20.56		Petrus Pharmaceuticals Pty Ltd	PP
5312N *NP*	Suppositories 1.4 g (for children), 12	3	3	..	*19.89	20.98		Petrus Pharmaceuticals Pty Ltd	PP
5313P *NP*	Suppositories 2.8 g (for adults), 12	3	3	..	*20.40	21.49		Petrus Pharmaceuticals Pty Ltd	PP

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	GLYCEROL **Authority required (STREAMLINED)** ***3643*** Continuing supply for a palliative care patient where constipation is a problem. **Note** Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.							
5314Q *NP*	Suppositories 700 mg (for infants), 12	3	..	..	*19.47	20.56	Petrus Pharmaceuticals Pty Ltd	PP
5315R *NP*	Suppositories 1.4 g (for children), 12	3	..	..	*19.89	20.98	Petrus Pharmaceuticals Pty Ltd	PP
5316T *NP*	Suppositories 2.8 g (for adults), 12	3	..	..	*20.40	21.49	Petrus Pharmaceuticals Pty Ltd	PP

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Musculo-skeletal system

Antiinflammatory and antirheumatic products

Antiinflammatory and antirheumatic products, non-steroids

Acetic acid derivatives and related substances

DICLOFENAC SODIUM
Authority required (STREAMLINED)
3645
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem.

5361E *NP*	Tablet 25 mg (enteric coated)	100	3	..	*12.74	13.83	a	APO-Diclofenac	TX
							a	Chem mart Diclofenac	CH
							a	Clonac 25	QA
							a	Diclofenac-GA	GM
							a	Diclofenac Sandoz	SZ
							a	Fenac 25	AF
							a	Terry White Chemists Diclofenac	TW
				B2.32	*15.06	13.83	a	Voltaren 25	NV
5362F *NP*	Tablet 50 mg (enteric coated)	50	3	..	10.82	11.91	a	APO-Diclofenac	TX
							a	Chem mart Diclofenac	CH
							a	Clonac 50	QA
							a	Diclofenac-GA	GM
							a	Diclofenac Sandoz	SZ
							a	Fenac	AF
							a	Terry White Chemists Diclofenac	TW
				B2.34	13.16	11.91	a	Voltaren 50	NV

DICLOFENAC SODIUM
Authority required
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem.

5363G *NP*	Suppository 100 mg	40	3	..	*24.92	26.01		Voltaren 100	NV

DICLOFENAC SODIUM
Authority required (STREAMLINED)
3646
Continuing supply for a palliative care patient where severe pain is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5364H *NP*	Tablet 25 mg (enteric coated)	100	..	..	*12.74	13.83	a	APO-Diclofenac	TX
							a	Chem mart Diclofenac	CH
							a	Clonac 25	QA
							a	Diclofenac-GA	GM

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Diclofenac Sandoz	SZ
							[a]	Fenac 25	AF
							[a]	Terry White Chemists Diclofenac	TW
				[B]2.32	*15.06	13.83	[a]	Voltaren 25	NV
5365J *NP*	Tablet 50 mg (enteric coated)	50	..	..	10.82	11.91	[a]	APO-Diclofenac	TX
							[a]	Chem mart Diclofenac	CH
							[a]	Clonac 50	QA
							[a]	Diclofenac-GA	GM
							[a]	Diclofenac Sandoz	SZ
							[a]	Fenac	AF
							[a]	Terry White Chemists Diclofenac	TW
				[B]2.34	13.16	11.91	[a]	Voltaren 50	NV

DICLOFENAC SODIUM
Authority required
Continuing supply for a palliative care patient where severe pain is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5366K *NP*	Suppository 100 mg	40	..	..	*24.92	26.01		Voltaren 100	NV

INDOMETHACIN
Authority required (STREAMLINED)
3645
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem.

5377B *NP*	Capsule 25 mg	100	3	..	*12.42	13.51	[a]	Arthrexin	AF
				[B]2.02	*14.44	13.51	[a]	Indocid	AS

INDOMETHACIN
Authority required
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem.

5378C *NP*	Suppository 100 mg	40	3	..	*22.50	23.59		Indocid	AS

INDOMETHACIN
Authority required (STREAMLINED)
3646
Continuing supply for a palliative care patient where severe pain is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5379D *NP*	Capsule 25 mg	100	..	..	*12.42	13.51	[a]	Arthrexin	AF
				[B]2.02	*14.44	13.51	[a]	Indocid	AS

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	INDOMETHACIN **Authority required** Continuing supply for a palliative care patient where severe pain is a problem. **Note** Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5380E *NP*	Suppository 100 mg	40	..	..	*22.50	23.59		Indocid	AS

Propionic acid derivatives

	IBUPROFEN **Authority required** Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem.								
5368M *NP*	Tablet 400 mg	90	3	..	*14.73	15.82		Brufen	AB
	IBUPROFEN **Authority required** Continuing supply for a palliative care patient where severe pain is a problem. **Note** Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5370P *NP*	Tablet 400 mg	90	..	..	*14.73	15.82		Brufen	AB
	NAPROXEN **Authority required (STREAMLINED)** ***3645*** Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem.								
5345H *NP*	Tablet 250 mg	100	3	..	*13.34	14.43	a	Inza 250	AF
				[B]2.24	*15.58	14.43	a	Naprosyn	RO
5346J *NP*	Tablet 500 mg	50	3	..	12.58	13.67	a	Inza 500	AF
				[B]1.30	13.88	13.67	a	Naprosyn	RO
5347K *NP*	Tablet 750 mg (sustained release)	28	3	..	12.08	13.17	a	Proxen SR 750	MD
				[B]1.22	13.30	13.17	a	Naprosyn SR750	RO
5348L *NP*	Tablet 1 g (sustained release)	28	3	..	13.96	15.05	a	Proxen SR 1000	MD
				[B]1.29	15.25	15.05	a	Naprosyn SR1000	RO
	NAPROXEN **Authority required (STREAMLINED)** ***3646*** Continuing supply for a palliative care patient where severe pain is a problem. **Note** Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5349M *NP*	Tablet 250 mg	100	..	..	*13.34	14.43	a	Inza 250	AF
				[B]2.24	*15.58	14.43	a	Naprosyn	RO
5350N	Tablet 500 mg	50	..	..	12.58	13.67	a	Inza 500	AF

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
NP									
				[B]1.30	13.88	13.67	[a]	Naprosyn	RO
5351P	Tablet 750 mg (sustained release)	28	..	..	12.08	13.17	[a]	Proxen SR 750	MD
NP									
				[B]1.22	13.30	13.17	[a]	Naprosyn SR750	RO
5352Q	Tablet 1 g (sustained release)	28	..	..	13.96	15.05	[a]	Proxen SR 1000	MD
NP									
				[B]1.29	15.25	15.05	[a]	Naprosyn SR1000	RO

NAPROXEN SODIUM
Authority required (STREAMLINED)
3645
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem.

Note
Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

5353R	Tablet 550 mg	50	3	..	12.77	13.86	[a]	Crysanal	MD
NP									
				[B]2.17	14.94	13.86	[a]	Anaprox 550	RO

NAPROXEN SODIUM
Authority required (STREAMLINED)
3646
Continuing supply for a palliative care patient where severe pain is a problem.

Note
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Note
Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

5354T	Tablet 550 mg	50	..	..	12.77	13.86	[a]	Crysanal	MD
NP									
				[B]2.17	14.94	13.86	[a]	Anaprox 550	RO

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Nervous system							
	Analgesics							
	Opioids							
	Natural opium alkaloids							
	MORPHINE SULFATE **Caution** The risk of drug dependence is high. **Authority required** Initial supply, for up to 3 months, for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics. **Note** Telephone approvals are limited to 1 month's therapy.							
5393W *NP*	Tablet 10 mg	20	2	..	14.31	15.40	Sevredol	MF
5394X *NP*	Tablet 20 mg	20	2	..	15.26	16.35	Sevredol	MF
	MORPHINE SULFATE **Caution** The risk of drug dependence is high. **Authority required** Continuing supply for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics. **Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised. Telephone approvals are limited to 1 month's therapy.							
5395Y *NP*	Tablet 10 mg	20	..	..	14.31	15.40	Sevredol	MF
5396B *NP*	Tablet 20 mg	20	..	..	15.26	16.35	Sevredol	MF
	MORPHINE SULFATE **Caution** The risk of drug dependence is high. **Authority required** Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics. **Note** Telephone approvals are limited to 1 month's therapy.							
5391R *NP*	Tablet 200 mg (controlled release)	28	2	..	121.86	35.40	MS Contin	MF
	MORPHINE SULFATE **Caution** The risk of drug dependence is high. **Authority required** Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics. **Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised. Telephone approvals are limited to 1 month's therapy.							

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
5392T *NP*	Tablet 200 mg (controlled release)	28	..	..	121.86	35.40	MS Contin	MF

Phenylpiperidine derivatives

FENTANYL

Caution

The risk of drug dependence is high.

Authority required

Initial supply for dose titration for breakthrough pain in a palliative care patient with cancer who is receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.

Note

No applications for increased repeats will be authorised.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Special Pricing Arrangements apply.

5401G *NP*	Lozenges 200 micrograms (as citrate), 3	3	..	..	*115.60	35.40	Actiq	OA
5402H *NP*	Lozenges 400 micrograms (as citrate), 3	3	..	..	*115.60	35.40	Actiq	OA
5403J *NP*	Lozenges 600 micrograms (as citrate), 3	3	..	..	*115.60	35.40	Actiq	OA
5404K *NP*	Lozenges 800 micrograms (as citrate), 3	3	..	..	*115.60	35.40	Actiq	OA
5405L *NP*	Lozenges 1200 micrograms (as citrate), 3	3	..	..	*115.60	35.40	Actiq	OA
5406M *NP*	Lozenges 1600 micrograms (as citrate), 3	3	..	..	*115.60	35.40	Actiq	OA

FENTANYL

Caution

The risk of drug dependence is high.

Authority required

Continuing supply for breakthrough pain in a palliative care patient with cancer who is receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.

Note

For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.
Telephone approvals are limited to 1 month's therapy.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Special Pricing Arrangements apply.

5407N *NP*	Lozenges 200 micrograms (as citrate), 30	2	..	..	*680.13	35.40	Actiq	OA
5408P *NP*	Lozenges 400 micrograms (as citrate), 30	2	..	..	*680.13	35.40	Actiq	OA
5409Q *NP*	Lozenges 600 micrograms (as citrate), 30	2	..	..	*680.13	35.40	Actiq	OA
5410R *NP*	Lozenges 800 micrograms (as citrate), 30	2	..	..	*680.13	35.40	Actiq	OA
5411T *NP*	Lozenges 1200 micrograms (as citrate), 30	2	..	..	*680.13	35.40	Actiq	OA
5412W	Lozenges 1600 micrograms (as citrate), 30	2	..	..	*680.13	35.40	Actiq	OA

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
NP								

Diphenylpropylamine derivatives

METHADONE HYDROCHLORIDE

Caution

The risk of drug dependence is high.

Authority required

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Telephone approvals are limited to 1 month's therapy.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5399E *NP*	Oral liquid 25 mg per 5 mL, 200 mL	1	2	..	18.92	20.01	Sigma Methadone Syrup	QA

METHADONE HYDROCHLORIDE

Caution

The risk of drug dependence is high.

Authority required

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.
Telephone approvals are limited to 1 month's therapy.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5400F *NP*	Oral liquid 25 mg per 5 mL, 200 mL	1	..	..	18.92	20.01	Sigma Methadone Syrup	QA

Other analgesics and antipyretics

Anilides

PARACETAMOL

Authority required (STREAMLINED)

3649

Initial supply, for up to 4 months, for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated.

5319Y *NP*	Suppositories 500 mg, 24	4	3	..	*84.46	35.40	Panadol	GC
5343F *NP*	Tablet 665 mg (modified release)	192	3	..	*16.64	17.73	Panadol Osteo	GC

PARACETAMOL

Authority required (STREAMLINED)

3650

Continuing supply for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated.

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5320B *NP*	Suppositories 500 mg, 24	4	..	..	*84.46	35.40	Panadol	GC
5344G *NP*	Tablet 665 mg (modified release)	192	..	..	*16.64	17.73	Panadol Osteo	GC

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Antiepileptics									
Antiepileptics									
Benzodiazepine derivatives									
	CLONAZEPAM **Authority required** Initial supply, for up to 4 months, for a palliative care patient for the prevention of epilepsy. **Note** No applications for increased repeats will be authorised.								
5337X *NP*	Tablet 500 micrograms	100	3	..	12.96	14.05	a	Paxam 0.5	AF
				B1.71	14.67	14.05	a	Rivotril	RO
5338Y *NP*	Tablet 2 mg	100	3	..	18.74	19.83	a	Paxam 2	AF
				B1.93	20.67	19.83	a	Rivotril	RO
5339B *NP*	Oral liquid 2.5 mg per mL, 10 mL	2	3	..	*15.04	16.13		Rivotril	RO
	CLONAZEPAM **Authority required** Continuing supply for a palliative care patient for the prevention of epilepsy. **Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.								
5340C *NP*	Tablet 500 micrograms	100	..	..	12.96	14.05	a	Paxam 0.5	AF
				B1.71	14.67	14.05	a	Rivotril	RO
5341D *NP*	Tablet 2 mg	100	..	..	18.74	19.83	a	Paxam 2	AF
				B1.93	20.67	19.83	a	Rivotril	RO
5342E *NP*	Oral liquid 2.5 mg per mL, 10 mL	2	..	..	*15.04	16.13		Rivotril	RO
Psycholeptics									
Anxiolytics									
Benzodiazepine derivatives									
	DIAZEPAM **Authority required** Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem. **Note** No applications for increased repeats will be authorised.								
5355W *NP*	Tablet 2 mg	50	3	..	7.72	8.81	a	Antenex 2	AF
							a	APO-Diazepam	TX
							a	Ranzepam	RA
							a	Valpam 2	QA
				B0.82	8.54	8.81	a	Valium	RO
5356X *NP*	Tablet 5 mg	50	3	..	7.85	8.94	a	Antenex 5	AF
							a	APO-Diazepam	TX
							a	Diazepam-GA	GM
							a	Ranzepam	RA
							a	Valpam 5	QA
				B0.85	8.70	8.94	a	Valium	RO

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	DIAZEPAM								
	Authority required								
	Continuing supply for a palliative care patient where anxiety is a problem.								
	Note								
	Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.								
5357Y	Tablet 2 mg	50	..	..	7.72	8.81	a	Antenex 2	AF
NP							a	APO-Diazepam	TX
							a	Ranzepam	RA
							a	Valpam 2	QA
				B0.82	8.54	8.81	a	Valium	RO
5358B	Tablet 5 mg	50	..	..	7.85	8.94	a	Antenex 5	AF
NP							a	APO-Diazepam	TX
							a	Diazepam-GA	GM
							a	Ranzepam	RA
							a	Valpam 5	QA
				B0.85	8.70	8.94	a	Valium	RO
	OXAZEPAM								
	Authority required								
	Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem.								
	Note								
	No applications for increased repeats will be authorised.								
5371Q	Tablet 15 mg	50	3	..	*8.88	9.97	a	Alepam 15	AF
NP				B5.38	*14.26	9.97	a	Serepax	QA
5372R	Tablet 30 mg	50	3	..	*8.88	9.97	a	Alepam 30	AF
NP							a	APO-Oxazepam	TX
							a	Murelax	FM
				B5.38	*14.26	9.97	a	Serepax	QA
	OXAZEPAM								
	Authority required								
	Continuing supply for a palliative care patient where anxiety is a problem.								
	Note								
	Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.								
5373T	Tablet 15 mg	50	..	..	*8.88	9.97	a	Alepam 15	AF
NP				B5.38	*14.26	9.97	a	Serepax	QA
5374W	Tablet 30 mg	50	..	..	*8.88	9.97	a	Alepam 30	AF
NP							a	APO-Oxazepam	TX
							a	Murelax	FM
				B5.38	*14.26	9.97	a	Serepax	QA

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Hypnotics and sedatives								
	Benzodiazepine derivatives								
	NITRAZEPAM								
	Authority required								
	Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem.								
	Note								
	No applications for increased repeats will be authorised.								
5359C	Tablet 5 mg	50	3	..	*9.22	10.31	a	Alodorm	AF
NP									
				[B]2.90	*12.12	10.31	a	Mogadon	VT
	NITRAZEPAM								
	Authority required								
	Continuing supply for a palliative care patient where insomnia is a problem.								
	Note								
	Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.								
5360D	Tablet 5 mg	50	..	..	*9.22	10.31	a	Alodorm	AF
NP									
				[B]2.90	*12.12	10.31	a	Mogadon	VT
	TEMAZEPAM								
	Authority required								
	Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem.								
	Note								
	No applications for increased repeats will be authorised.								
5375X	Tablet 10 mg	50	3	..	*8.50	9.59	a	APO-Temazepam	TX
NP									
							a	Temaze	AF
							a	Temtabs	FM
				[B]2.42	*10.92	9.59	a	Normison	QA
	TEMAZEPAM								
	Authority required								
	Continuing supply for a palliative care patient where insomnia is a problem.								
	Note								
	Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.								
5376Y	Tablet 10 mg	50	..	..	*8.50	9.59	a	APO-Temazepam	TX
NP									
							a	Temaze	AF
							a	Temtabs	FM
				[B]2.42	*10.92	9.59	a	Normison	QA

Pharmaceutical Benefits for Dental Use

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Alimentary tract and metabolism

Stomatological preparations

Stomatological preparations

Antiinfectives and antiseptics for local oral treatment

AMPHOTERICIN

3306B	Lozenge 10 mg	20	..	..	12.03	13.12	Fungilin	QA

NYSTATIN

3343Y	Oral suspension 100,000 units per mL, 24 mL	‡1	..	..	11.14	12.23	Mycostatin	FM
							Nilstat	QA

Other agents for local oral treatment

BENZYDAMINE HYDROCHLORIDE

Restricted benefit

Radiation induced mucositis.

5032W	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	‡1	..	..	22.26	23.35	Difflam	IA

Drugs for functional gastrointestinal disorders

Belladonna and derivatives, plain

Belladonna alkaloids, tertiary amines

ATROPINE

5022H	Injection containing atropine sulfate 600 micrograms in 1 mL	10	..	..	20.54	21.63	Pfizer Australia Pty Ltd	PF

Propulsives

Propulsives

METOCLOPRAMIDE HYDROCHLORIDE

5151D	Tablet 10 mg	25	..	..	8.20	9.29	Pramin	AF
				[B]3.02	11.22	9.29	Maxolon	VT
5153F	Injection 10 mg in 2 mL	10	..	..	12.99	14.08	Maxolon	VT

Antiemetics and antinauseants

Antiemetics and antinauseants

Other antiemetics

PROCHLORPERAZINE

Caution

Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

5205Y	Tablet containing prochlorperazine maleate 5 mg	25	..	..	9.46	10.55	[a] APO-Prochlorperazine	TX
							[a] Pharmacor Prozine 5	CR
							[a] ProCalm	QA
							[a] Prochlorperazine-GA	GM
							[a] Prochlorperazine GH	GQ
							[a] Prochlorperazine-PS	FZ

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
						[a]	Stemzine	AV
				[B]3.45	12.91	10.55 [a]	Stemetil	SW
5206B	Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	..	..	16.82	17.91	Stemetil	SW
5208D	Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5	‡1	..	..	19.93	21.02	Stemetil	SW
	PROMETHAZINE HYDROCHLORIDE							
3374N	Injection 50 mg in 2 mL	10	..	..	*22.32	23.41	Hospira Pty Limited	HH

Antidiarrheals, intestinal antiinflammatory/ antiinfective agents

Intestinal antiinfectives

Antibiotics

	NYSTATIN							
3342X	Tablet 500,000 units	50	..	..	17.98	19.07	Nilstat	QA
3345C	Capsule 500,000 units	50	..	..	17.98	19.07	Nilstat	QA

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Blood and blood forming organs								
	Blood substitutes and perfusion solutions								
	I.V. solutions								
	Solutions for parenteral nutrition								
	GLUCOSE								
5005K	I.V. infusion 139 mmol (anhydrous) per 500 mL (5%), 500 mL	5	..	..	*17.87	18.96	[a]	B. Braun Australia Pty Ltd	BR
							[a]	Fresenius Kabi Australia Pty Limited	PK
5106R	I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	..	..	*22.82	23.91	[a]	B. Braun Australia Pty Ltd	BR
							[a]	Baxter Healthcare Pty Ltd	BX
							[a]	Fresenius Kabi Australia Pty Limited	PK
	Solutions affecting the electrolyte balance								
	SODIUM CHLORIDE								
5021G	I.V. infusion 77 mmol per 500 mL (0.9%), 500 mL	5	..	..	*13.02	14.11	[a]	B. Braun Australia Pty Ltd	BR
							[a]	Fresenius Kabi Australia Pty Limited	PK
5212H	I.V. infusion 154 mmol per L (0.9%), 1 L	5	..	..	*15.92	17.01	[a]	B. Braun Australia Pty Ltd	BR
							[a]	Baxter Healthcare Pty Ltd	BX
							[a]	Fresenius Kabi Australia Pty Limited	PK
5213J	I.V. infusion 513 mmol per L (3%), 1 L	2	..	..	*12.12	13.21		Baxter Healthcare Pty Ltd	BX
	SODIUM CHLORIDE with GLUCOSE								
5214K	I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	..	..	*23.52	24.61		Baxter Healthcare Pty Ltd	BX
5215L	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	..	..	*28.77	29.86		Baxter Healthcare Pty Ltd	BX
5216M	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%-2.5%), 500 mL	5	..	..	*28.77	29.86		Baxter Healthcare Pty Ltd	BX

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Cardiovascular system								
	Cardiac therapy								
	Antiarrhythmics, class I and III								
	Antiarrhythmics, class IB								
	LIGNOCAINE HYDROCHLORIDE								
5142P	Injection 100 mg in 5 mL	5	..	..	37.33	35.40		Pfizer Australia Pty Ltd	PF
	Cardiac stimulants excl. cardiac glycosides								
	Adrenergic and dopaminergic agents								
	ADRENALINE								
5004J	Injection 1 mg in 1 mL (1 in 1,000)	5	..	..	20.34	21.43		Link Medical Products Pty Ltd	LM
	Vasodilators used in cardiac diseases								
	Organic nitrates								
	GLYCERYL TRINITRATE								
5108W	Tablets 600 micrograms, 100	‡1	..	..	14.83	15.92	a	Lycinate	FM
				[B]2.94	17.77	15.92	a	Anginine Stabilised	QA

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Dermatologicals

Corticosteroids, dermatological preparations

Corticosteroids, plain

Corticosteroids, weak (group I)

HYDROCORTISONE ACETATE

Restricted benefit

Treatment of corticosteroid-responsive dermatoses.

5111B	Cream 10 mg per g (1%), 30 g	‡1	..	..	8.89	9.98	a	Cortic-DS 1%	FM
				B2.69	11.58	9.98	a	Sigmacort	QA
5112C	Topical ointment 10 mg per g (1%), 30 g	‡1	..	..	8.89	9.98	a	Cortic-DS 1%	FM
				B2.69	11.58	9.98	a	Sigmacort	QA
5113D	Cream 10 mg per g (1%), 50 g	‡1	..	..	8.56	9.65	a	Cortic-DS 1%	FM
				B2.70	11.26	9.65	a	Sigmacort	QA
5114E	Topical ointment 10 mg per g (1%), 50 g	‡1	..	..	8.56	9.65	a	Cortic-DS 1%	FM
				B2.70	11.26	9.65	a	Sigmacort	QA

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Systemic hormonal preparations, excl. sex hormones and insulins

Corticosteroids for systemic use

Corticosteroids for systemic use, plain

Glucocorticoids

BETAMETHASONE ACETATE with BETAMETHASONE SODIUM PHOSPHATE
Restricted benefit
For local intra-articular or peri-articular infiltration;
Keloid;
Lichen planus hypertrophic.

5034Y	Injection 3 mg-3.9 mg (equivalent to 5.7 mg betamethasone) in 1 mL	5	..	..	25.00	26.09		Celestone Chronodose	MK

HYDROCORTISONE SODIUM SUCCINATE
Restricted benefit
For use in a hospital.

5118J	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	6	..	..	*36.72	35.40		Solu-Cortef	PF
5119K	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	6	..	..	*58.74	35.40		Solu-Cortef	PF

METHYLPREDNISOLONE ACETATE
Restricted benefit
For local intra-articular or peri-articular infiltration.

5148Y	Injection 40 mg in 1 mL	5	..	..	21.38	22.47	a	Depo-Nisolone	FZ
				[B]0.60	21.98	22.47	a	Depo-Medrol	PF

TRIAMCINOLONE ACETONIDE
Restricted benefit
For local intra-articular or peri-articular infiltration;
Keloid;
Lichen planus hypertrophic.

5233K	Injection 10 mg in 1 mL	5	..	..	25.00	26.09		Kenacort-A10	QA

Pancreatic hormones

Glycogenolytic hormones

Glycogenolytic hormones

GLUCAGON HYDROCHLORIDE

5105Q	Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	..	..	45.63	35.40		GlucaGen Hypokit	NO

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Antiinfectives for systemic use

Antibacterials for systemic use

Tetracyclines

Tetracyclines

DOXYCYCLINE

Note

Pharmaceutical benefits that have the form doxycycline tablet 100 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 100 mg (as monohydrate) are equivalent for the purposes of substitution.

3321T	Tablet 100 mg (as hydrochloride)	7	..	..	8.36	9.45	[a]	Doxsig	QA
							[a]	Doxy-100	GM
							[a]	Doxylin 100	AF
5082L	Tablet 100 mg (as monohydrate)	7	..	..	8.36	9.45	[a]	Chem mart Doxycycline	CH
							[a]	Doxyhexal	SZ
							[a]	GenRx Doxycycline	GX
							[a]	Terry White Chemists Doxycycline	TW

DOXYCYCLINE

3322W	Capsule 100 mg (as hydrochloride)	7	..	..	8.36	9.45	[a]	Mayne Pharma Doxycycline	YT
				[B]1.10	9.46	9.45	[a]	Doryx	YN

Beta-lactam antibacterials, penicillins

Penicillins with extended spectrum

AMOXYCILLIN

3300Q	Capsule 500 mg	20	..	..	9.03	10.12	[a]	Alphamox 500	AF
							[a]	Amoxycillin-GA	GM
							[a]	Amoxycillin generichealth 500	GQ
							[a]	Amoxycillin Ranbaxy	RA
							[a]	Amoxycillin Sandoz	SZ
							[a]	APO-Amoxycillin	TX
							[a]	Chem mart Amoxycillin	CH
							[a]	Cilamox	QA
							[a]	GenRx Amoxycillin	GX
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.89	9.92	10.12	[a]	Amoxil	GK
3301R	Capsule 250 mg	20	..	..	7.73	8.82	[a]	Alphamox 250	AF
							[a]	Amoxycillin-GA	GM
							[a]	Amoxycillin Ranbaxy	RA
							[a]	Amoxycillin Sandoz	SZ
							[a]	APO-Amoxycillin	TX
							[a]	Chem mart Amoxycillin	CH
							[a]	Cilamox	QA

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	GenRx Amoxycillin	GX
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.88	8.61	8.82	[a]	Amoxil	GK
3302T	Powder for syrup 125 mg per 5 mL, 100 mL	‡1	..	..	#10.17	11.61	[a]	Alphamox 125	AF
							[a]	Amoxycillin Sandoz	SZ
							[a]	Bgramin	GM
							[a]	Chem mart Amoxycillin	CH
							[a]	GenRx Amoxycillin	GX
							[a]	Ranmoxy	RA
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.89	#11.06	11.61	[a]	Amoxil	GK
3393N	Powder for syrup 250 mg per 5 mL, 100 mL	‡1	..	..	#10.68	12.12	[a]	Alphamox 250	AF
							[a]	Amoxycillin Sandoz	SZ
							[a]	Bgramin	GM
							[a]	Chem mart Amoxycillin	CH
							[a]	Cilamox	QA
							[a]	GenRx Amoxycillin	GX
							[a]	Ranmoxy	RA
							[a]	Terry White Chemists Amoxycillin	TW
				[B]0.87	#11.55	12.12	[a]	Amoxil Forte	GK
5225B	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡1	..	..	#12.54	13.98		Maxamox	SZ
	AMPICILLIN								
3313J	Powder for injection 500 mg	5	..	..	10.85	11.94	[a]	Austrapen	LN
							[a]	Ibimicyn	TS
3314K	Powder for injection 1 g	5	..	..	13.69	14.78	[a]	Aspen Ampicyn	AS
							[a]	Austrapen	LN
							[a]	Ibimicyn	TS

Beta-lactamase sensitive penicillins

	BENZATHINE BENZYLPENICILLIN								
5027N	Injection 900 mg in 2.3 mL single use pre-filled syringe	10	..	..	293.11	35.40		Bicillin L-A	PF
	BENZYLPENICILLIN								
3398W	Powder for injection 600 mg	10	..	..	*42.92	35.40		BenPen	CS
3399X	Powder for injection 3 g	10	..	..	*66.92	35.40		BenPen	CS
	PHENOXYMETHYLPENICILLIN								
3360W	Tablet 250 mg	50	..	..	*11.32	12.41		Abbocillin-VK Filmtab	QA
3361X	Tablet 500 mg	50	..	..	*13.66	14.75		Abbocillin-VK Filmtab	QA
3363B	Capsule 250 mg	50	..	..	11.16	12.25	[a]	Cilicaine VK	FM
							[a]	Cilopen VK	GM
								LPV	VT
3364C	Capsule 500 mg	50	..	..	13.47	14.56	[a]	Cilicaine VK	FM

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Cilopen VK	GM
								LPV	VT
5012T	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	2	..	..	*21.60	22.69	[a]	Cilicaine V	FM
				[B]1.90	*23.50	22.69	[a]	Abbocillin-V	QA
5024K	Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL	2	..	..	*#16.76	18.20		Phenoxymethyl-penicillin-AFT	AE
5029Q	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL	2	..	..	*#19.32	20.76		Phenoxymethyl-penicillin-AFT	AE
	PROCAINE PENICILLIN								
3371K	Injection 1.5 g	5	..	..	92.22	35.40		Cilicaine	QA

Beta-lactamase resistant penicillins

DICLOXACILLIN
Restricted benefit
Serious staphylococcal infections.

5096F	Capsule 250 mg	24	..	..	11.19	12.28	[a]	Dicloxsig	QA
							[a]	Distaph 250	AF
5097G	Capsule 500 mg	24	..	..	16.41	17.50	[a]	Diclocil	BQ
							[a]	Dicloxsig	QA
							[a]	Distaph 500	AF

FLUCLOXACILLIN
Caution
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

5094D	Powder for injection 500 mg	5	..	..	12.76	13.85	[a]	Flubiclox	TS
							[a]	Flucil	AS
5095E	Powder for injection 1 g	5	..	..	16.33	17.42	[a]	Flubiclox	TS
							[a]	Flucil	AS
							[a]	Hospira Pty Limited	HH

FLUCLOXACILLIN
Caution
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit
Serious staphylococcal infections.

5090X	Capsule 250 mg (as sodium)	24	..	..	11.19	12.28	[a]	Flopen	AS
							[a]	Staphylex 250	AF
5091Y	Capsule 500 mg (as sodium)	24	..	..	16.41	17.50	[a]	Flopen	AS
							[a]	Staphylex 500	AF
5257Q	Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL	‡1	..	..	#16.05	17.49		Flucil	LN
5258R	Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL	‡1	..	..	#19.58	21.02		Flucil	LN

Combinations of penicillins, incl. beta-lactamase inhibitors

AMOXYCILLIN with CLAVULANIC ACID
Caution
Hepatotoxicity has been reported with this drug.

Restricted benefit
Infections where resistance to amoxycillin is suspected;

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Infections where resistance to amoxycillin is proven.								
5006L	Tablet 875 mg-125 mg	10	..	..	11.63	12.72	a	Amoxycillin/ Clavulanic Acid 875/125 generichealth	GQ
							a	Chem mart Amoxycillin and Clavulanic Acid	CH
							a	Clamoxyl Duo forte	AL
							a	Clavycillin 875/125	CR
							a	Curam Duo Forte 875/125	SZ
							a	GA-Amclav Forte 875/125	GM
							a	GenRx Amoxycillin and Clavulanic Acid	GX
							a	Moxiclav Duo Forte 875/125	QA
							a	Terry White Chemists Amoxycillin and Clavulanic Acid	TW
				[B]1.56	13.19	12.72	a	Augmentin Duo forte	GK
5008N	Tablet 500 mg-125 mg	10	..	..	10.08	11.17	a	Amoxycillin/ Clavulanic Acid 500/125 generichealth	GQ
							a	APO-Amoxycillin/ Clavulanic Acid 500/125	TX
							a	Clamoxyl Duo	AL
							a	Curam Duo 500/125	SZ
							a	GA-Amclav 500/125	GM
							a	Moxiclav Duo 500/125	QA
				[B]1.57	11.65	11.17	a	Augmentin Duo	GK
5009P	Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL	‡1	..	..	#11.25	12.69	a	Clamoxyl	AL
							a	Curam	SZ
				[B]1.58	#12.83	12.69	a	Augmentin	GK
5011R	Powder for syrup 400 mg-57 mg per 5 mL, 60 mL	‡1	..	..	#12.22	13.66	a	Clamoxyl Duo 400	AL
							a	Curam Duo	SZ
				[B]1.58	#13.80	13.66	a	Augmentin Duo 400	GK
	TICARCILLIN with CLAVULANIC ACID								
	Restricted benefit								
	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.								
5230G	Powder for injection 3 g-100 mg (solvent required) (code 7043Q applies to above item with approved solvent)	10	..	..	163.32	35.40		Timentin	GK

Other beta-lactam antibacterials
First-generation cephalosporins

	CEFALOTIN								
3376Q	Powder for injection 1 g	10	..	..	26.25	27.34	a	Cefalotin Sandoz	SZ

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Hospira Pty Limited	HH
							[a]	Keflin Neutral	AS
	CEPHALEXIN								
3317N	Capsule 250 mg	20	..	..	7.92	9.01	[a]	Cefalexin Sandoz	SZ
							[a]	Cephalexin generichealth	GQ
							[a]	Cephalexin-PS	FZ
							[a]	Cephatrust 250	MI
							[a]	Chem mart Cephalexin	CH
							[a]	Cilex	GM
							[a]	GenRx Cephalexin	GX
							[a]	Ialex	LN
							[a]	Ibilex 250	AF
							[a]	Pharmacor Cephalexin 250	CR
							[a]	Rancef	RA
							[a]	Terry White Chemists Cephalexin	TW
				[B]2.03	9.95	9.01	[a]	Keflex	AS
3318P	Capsule 500 mg	20	..	..	9.10	10.19	[a]	Cefalexin Sandoz	SZ
							[a]	Cephabell	BF
							[a]	Cephalexin generichealth	GQ
							[a]	Cephalexin-PS	FZ
							[a]	Cephatrust 500	MI
							[a]	Chem mart Cephalexin	CH
							[a]	Cilex	GM
							[a]	GenRx Cephalexin	GX
							[a]	Ialex	LN
							[a]	Ibilex 500	AF
							[a]	Pharmacor Cephalexin 500	CR
							[a]	Rancef	RA
							[a]	Terry White Chemists Cephalexin	TW
				[B]2.73	11.83	10.19	[a]	Keflex	AS
3319Q	Granules for syrup 125 mg per 5 mL, 100 mL	‡1	..	..	#10.78	12.22	[a]	APO-Cephalexin	TX
							[a]	Cefalexin Sandoz	SZ
							[a]	Chem mart Cephalexin	CH
							[a]	Cilex	GM
							[a]	GenRx Cephalexin	GX
							[a]	Ialex	LN
							[a]	Ibilex 125	AF
							[a]	Terry White Chemists Cephalexin	TW
				[B]2.20	#12.98	12.22	[a]	Keflex	AS
3320R	Granules for syrup 250 mg per 5 mL, 100 mL	‡1	..	..	#11.65	13.09	[a]	APO-Cephalexin	TX
							[a]	Cefalexin Sandoz	SZ
							[a]	Chem mart Cephalexin	CH

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
							[a]	Cilex	GM
							[a]	GenRx Cephalexin	GX
							[a]	Ialex	LN
							[a]	Ibilex 250	AF
							[a]	Terry White Chemists Cephalexin	TW
				[B]2.70	#14.35	13.09	[a]	Keflex	AS

Second-generation cephalosporins

CEFACLOR

Caution

Serum sickness-like reactions have been reported with this drug, especially in children.

5045M	Tablet 375 mg (sustained release)	10	..	..	11.33	12.42	[a]	Cefaclor-GA	GN
							[a]	Cefaclor GH	GQ
							[a]	Chem mart Cefaclor CD	CH
							[a]	GenRx Cefaclor CD	GX
							[a]	Karlor CD	LN
							[a]	Keflor CD	AF
							[a]	Ozcef	RA
							[a]	Terry White Chemists Cefaclor CD	TW
				[B]3.93	15.26	12.42	[a]	Ceclor CD	AS
5046N	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡1	..	..	#12.45	13.89	[a]	Aclor 125	QA
							[a]	Cefaclor Sandoz	SZ
							[a]	Chem mart Cefaclor	CH
							[a]	GenRx Cefaclor	GX
							[a]	Keflor	AF
							[a]	Ozcef	RA
							[a]	Terry White Chemists Cefaclor	TW
				[B]3.16	#15.61	13.89	[a]	Ceclor	AS
5047P	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡1	..	..	#12.69	14.13	[a]	Aclor 250	QA
							[a]	Cefaclor Sandoz	SZ
							[a]	Chem mart Cefaclor	CH
							[a]	GenRx Cefaclor	GX
							[a]	Keflor	AF
							[a]	Ozcef	RA
							[a]	Terry White Chemists Cefaclor	TW
				[B]3.31	#16.00	14.13	[a]	Ceclor	AS

CEFUROXIME AXETIL

5052X	Tablet 250 mg (base)	14	..	..	18.62	19.71		Zinnat	GK

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Third-generation cephalosporins								
	CEFOTAXIME								
	Restricted benefit								
	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.								
5048Q	Powder for injection 1 g	10	..	..	*26.32	27.41	a	Cefotaxime Sandoz	SZ
				..	26.44	27.53	a	Hospira Pty Limited	HH
5049R	Powder for injection 2 g	10	..	..	*42.92	35.40	a	Cefotaxime Sandoz	SZ
				..	43.02	35.40	a	Hospira Pty Limited	HH
	Sulfonamides and trimethoprim								
	Combinations of sulfonamides and trimethoprim, incl. derivatives								
	TRIMETHOPRIM with SULFAMETHOXAZOLE								
	Caution								
	There is an increased risk of severe adverse reactions with this combination in the elderly.								
3390K	Tablet 160 mg-800 mg	10	..	..	9.24	10.33	a	Bactrim DS	RO
							a	Resprim Forte	AF
				[B]1.46	10.70	10.33	a	Septrin Forte	QA
3391L	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡1	..	..	8.93	10.02		Bactrim	RO
				[B]1.79	10.72	10.02		Septrin	QA
	Macrolides, lincosamides and streptogramins								
	Macrolides								
	ERYTHROMYCIN								
3325B	Capsule 250 mg	25	..	..	10.69	11.78	a	Mayne Pharma Erythromycin	YT
				[B]2.38	13.07	11.78	a	Eryc	YN
	ERYTHROMYCIN ETHYL SUCCINATE								
3334L	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	‡1	..	..	#14.52	15.96	a	E-Mycin 200	AF
				[B]2.71	#17.23	15.96	a	E.E.S. 200	LM
3336N	Tablet 400 mg (base)	25	..	..	10.69	11.78	a	E-Mycin	AF
				[B]2.66	13.35	11.78	a	E.E.S. 400 Filmtab	LM
3337P	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	‡1	..	..	#16.03	17.47	a	E-Mycin 400	AF
				[B]2.73	#18.76	17.47	a	E.E.S. Granules	LM
	ERYTHROMYCIN LACTOBIONATE								
5088T	Powder for I.V. infusion 1 g (base)	5	..	..	*98.62	35.40		Erythrocin-I.V.	LM
	ROXITHROMYCIN								
5259T	Tablet for oral suspension 50 mg	10	..	..	12.89	13.98		Rulide D	SW
5260W	Tablet 150 mg	10	..	..	9.76	10.85	a	APO-Roxithromycin	TX
							a	Biaxsig	AV
							a	Chem mart Roxithromycin	CH
							a	Roxar 150	QA
							a	Roximycin	AF
							a	Roxithromycin-GA	GM
							a	Roxithromycin Sandoz	SZ
							a	Terry White Chemists	TW

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Roxithromycin	
				[B]1.71	11.47	10.85	[a]	Rulide	SW
5261X	Tablet 300 mg	5	..	..	9.76	10.85	[a]	APO-Roxithromycin	TX
							[a]	Biaxsig	AV
							[a]	Chem mart Roxithromycin	CH
							[a]	Roxar 300	QA
							[a]	Roximycin	AF
							[a]	Roxithromycin-GA	GM
							[a]	Roxithromycin Sandoz	SZ
							[a]	Terry White Chemists Roxithromycin	TW
				[B]1.71	11.47	10.85	[a]	Rulide	SW

Lincosamides

CLINDAMYCIN
Restricted benefit
Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.

5057E	Capsule 150 mg	24	..	..	19.75	20.84	[a]	Cleocin	FZ
				[B]1.37	21.12	20.84	[a]	Dalacin C	PF

LINCOMYCIN

5144R	Injection 600 mg in 2 mL	5	..	..	33.74	34.83		Lincocin	PF

Other antibacterials

Glycopeptide antibacterials

VANCOMYCIN
Restricted benefit
Prophylaxis of endocarditis in patients hypersensitive to penicillin.

3323X	Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)	2	..	..	*16.52	17.61	[a]	Hospira Pty Limited	HH
							[a]	Vancocin CP	AS
							[a]	Vancomycin Alphapharm	AF
							[a]	Vancomycin Sandoz	SZ
							[a]	Vycin IV	WQ
5083M	Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)	1	..	..	16.52	17.61	[a]	Hospira Pty Limited	HH
							[a]	Vancomycin Alphapharm	AF
							[a]	Vancomycin Sandoz	SZ
							[a]	Vycin IV	WQ

Imidazole derivatives

METRONIDAZOLE

3339R	Tablet 200 mg	21	..	..	7.88	8.97	[a]	Metrogyl 200	AF
							[a]	Metronide 200	AV
				[B]2.30	10.18	8.97	[a]	Flagyl	SW
5157K	Suppositories 500 mg, 10	‡1	..	..	23.16	24.25		Flagyl	SW

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	METRONIDAZOLE **Restricted benefit** Treatment of anaerobic infections.								
5155H	Tablet 400 mg	21	..	..	9.85	10.94	[a]	Metrogyl 400	AF
							[a]	Metronide 400	AV
				[B]2.30	12.15	10.94	[a]	Flagyl	SW
	METRONIDAZOLE **Restricted benefit** Treatment, in a hospital, of acute anaerobic sepsis.								
5154G	I.V. infusion 500 mg in 100 mL	5	..	..	*30.67	31.76	[a]	Baxter Healthcare Pty Ltd	BX
				..	*31.70	32.79	[a]	DBL Metronidazole Intravenous Infusion	HH
	METRONIDAZOLE BENZOATE								
3341W	Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡1	..	..	18.82	19.91		Flagyl S	SW

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Musculo-skeletal system								
	Antiinflammatory and antirheumatic products								
	Antiinflammatory and antirheumatic products, non-steroids								
	Acetic acid derivatives and related substances								
	DICLOFENAC SODIUM								
5079H	Suppository 100 mg	40	..	..	*24.92	26.01		Voltaren 100	NV
	DICLOFENAC SODIUM								
	Restricted benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component;								
	Bone pain due to malignant disease.								
5076E	Tablet 25 mg (enteric coated)	100	..	..	*12.74	13.83	a	APO-Diclofenac	TX
							a	Chem mart Diclofenac	CH
							a	Clonac 25	QA
							a	Diclofenac-GA	GM
							a	Diclofenac Sandoz	SZ
							a	Fenac 25	AF
							a	Terry White Chemists Diclofenac	TW
				B2.32	*15.06	13.83	a	Voltaren 25	NV
5077F	Tablet 50 mg (enteric coated)	50	..	..	10.82	11.91	a	APO-Diclofenac	TX
							a	Chem mart Diclofenac	CH
							a	Clonac 50	QA
							a	Diclofenac-GA	GM
							a	Diclofenac Sandoz	SZ
							a	Fenac	AF
							a	Terry White Chemists Diclofenac	TW
				B2.34	13.16	11.91	a	Voltaren 50	NV
	INDOMETHACIN								
5128X	Suppository 100 mg	40	..	..	*22.50	23.59		Indocid	AS
	INDOMETHACIN								
	Restricted benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component;								
	Bone pain due to malignant disease.								
5126T	Capsule 25 mg	100	..	..	*12.42	13.51	a	Arthrexin	AF
				B2.02	*14.44	13.51	a	Indocid	AS
	Oxicams								
	PIROXICAM								
	Restricted benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component.								

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
5201R	Dispersible tablet 10 mg	50	..	..	12.20	13.29		Mobilis D-10	AF
5202T	Dispersible tablet 20 mg	25	..	..	11.92	13.01	a	Mobilis D-20	AF
				B2.49	14.41	13.01	a	Feldene-D	PF
5203W	Capsule 10 mg	50	..	..	12.20	13.29	a	Chem mart Piroxicam	CH
							a	GenRx Piroxicam	GX
							a	Mobilis 10	AF
							a	Terry White Chemists Piroxicam	TW
				B2.52	14.72	13.29	a	Feldene	PF
5204X	Capsule 20 mg	25	..	..	11.92	13.01	a	Chem mart Piroxicam	CH
							a	GenRx Piroxicam	GX
							a	Mobilis 20	AF
							a	Terry White Chemists Piroxicam	TW
				B2.49	14.41	13.01	a	Feldene	PF

Propionic acid derivatives

IBUPROFEN

5124Q	Tablet 400 mg	30	..	..	9.19	10.28		Brufen	AB

IBUPROFEN
Restricted benefit
Chronic arthropathies (including osteoarthritis) with an inflammatory component;
Bone pain due to malignant disease.

5123P	Tablet 400 mg	90	..	..	*14.73	15.82		Brufen	AB

KETOPROFEN

5139L	Suppository 100 mg	40	..	..	*25.30	26.39		Orudis	SW

KETOPROFEN
Restricted benefit
Chronic arthropathies (including osteoarthritis) with an inflammatory component.

5136H	Capsule 200 mg (sustained release)	28	..	..	19.10	20.19	a	Oruvail SR	AV
				B2.21	21.31	20.19	a	Orudis SR 200	SW

NAPROXEN
Restricted benefit
Chronic arthropathies (including osteoarthritis) with an inflammatory component;
Bone pain due to malignant disease.

5176K	Tablet 250 mg	100	..	..	*13.34	14.43	a	Inza 250	AF
				B2.24	*15.58	14.43	a	Naprosyn	RO
5177L	Tablet 500 mg	50	..	..	12.58	13.67	a	Inza 500	AF
				B1.30	13.88	13.67	a	Naprosyn	RO
5178M	Tablet 750 mg (sustained release)	28	..	..	12.08	13.17	a	Proxen SR 750	MD
				B1.22	13.30	13.17	a	Naprosyn SR750	RO
5179N	Tablet 1 g (sustained release)	28	..	..	13.96	15.05	a	Proxen SR 1000	MD
				B1.29	15.25	15.05	a	Naprosyn SR1000	RO

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	NAPROXEN SODIUM								
	Restricted benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component;								
	Bone pain due to malignant disease.								
	Note								
	Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.								
5186Y	Tablet 550 mg	50	..	..	12.77	13.86	a	Crysanal	MD
				[B]2.17	14.94	13.86	a	Anaprox 550	RO

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Nervous system								
	Analgesics								
	Opioids								
	Natural opium alkaloids								
	CODEINE PHOSPHATE								
	Note								
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5063L	Tablet 30 mg	20	..	..	16.87	17.96		Fawns and McAllan Proprietary Limited	FM
	CODEINE PHOSPHATE with PARACETAMOL								
3316M	Tablet 30 mg-500 mg	20	..	..	7.48	8.57	[a]	APO-Paracetamol/Codeine 500/30	TX
							[a]	Codalgin Forte	FM
							[a]	Codapane Forte	AL
							[a]	Comfarol Forte	SZ
							[a]	Prodeine Forte	AV
				[B]1.88	9.36	8.57	[a]	Panadeine Forte	SW
	HYDROMORPHONE HYDROCHLORIDE								
	Caution								
	The risk of drug dependence is high.								
	Restricted benefit								
	Severe disabling pain not responding to non-narcotic analgesics.								
	Note								
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5115F	Tablet 2 mg	20	..	..	17.10	18.19		Dilaudid	MF
5116G	Tablet 4 mg	20	..	..	19.85	20.94		Dilaudid	MF
5117H	Tablet 8 mg	20	..	..	30.03	31.12		Dilaudid	MF
5132D	Oral liquid 1 mg per mL, 473 mL	1	..	..	63.70	35.40		Dilaudid	MF
	MORPHINE HYDROCHLORIDE								
	Caution								
	The risk of drug dependence is high.								
	Restricted benefit								
	Severe disabling pain not responding to non-narcotic analgesics.								
	Note								
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5237P	Oral solution 2 mg per mL, 200 mL	1	..	..	20.33	21.42		Ordine 2	MF
5238Q	Oral solution 5 mg per mL, 200 mL	1	..	..	22.73	23.82		Ordine 5	MF
5239R	Oral solution 10 mg per mL, 200 mL	1	..	..	26.86	27.95		Ordine 10	MF
	MORPHINE SULFATE								
	Caution								
	The risk of drug dependence is high.								
	Note								
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5168B	Injection 10 mg in 1 mL	5	..	..	13.99	15.08		Hospira Pty Limited	HH

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
5169C	Injection 15 mg in 1 mL	5	..	..	14.35	15.44		Hospira Pty Limited	HH
5170D	Injection 30 mg in 1 mL	5	..	..	15.77	16.86		Hospira Pty Limited	HH
	MORPHINE SULFATE								
	Caution								
	The risk of drug dependence is high.								
	Restricted benefit								
	Severe disabling pain not responding to non-narcotic analgesics.								
	Note								
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5163R	Tablet 30 mg	20	..	..	14.03	15.12		Anamorph	FM
	OXYCODONE								
	Caution								
	The risk of drug dependence is high.								
	Restricted benefit								
	Severe disabling pain not responding to non-narcotic analgesics.								
	Note								
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5194J	Suppository 30 mg	12	..	..	43.66	35.40		Proladone	PL
	OXYCODONE HYDROCHLORIDE								
	Caution								
	The risk of drug dependence is high.								
	Restricted benefit								
	Severe disabling pain not responding to non-narcotic analgesics.								
	Note								
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5190E	Oral solution 5 mg per 5 mL, 250 mL	1	..	..	20.72	21.81		OxyNorm Liquid 5mg/5mL	MF
5191F	Capsule 5 mg	20	..	..	12.30	13.39		OxyNorm	MF
5195K	Tablet 5 mg	20	..	..	12.30	13.39		Endone	QA
5197M	Capsule 10 mg	20	..	..	15.42	16.51		OxyNorm	MF

Other opioids

	TRAMADOL HYDROCHLORIDE								
	Restricted benefit								
	For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed;								
	For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed.								
5232J	Capsule 50 mg	20	..	..	8.39	9.48	[a]	APO-Tramadol	TX
							[a]	Chem mart Tramadol	CH
							[a]	GA Tramadol 50mg	GM
							[a]	GenRx Tramadol	GX
							[a]	Lodam 50	ZP
							[a]	Terry White Chemists Tramadol	TW
							[a]	Tramadol Sandoz	SZ
							[a]	Tramedo	AF
							[a]	Zydol	QA
				[B]1.83	10.22	9.48	[a]	Tramal	CS

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	TRAMADOL HYDROCHLORIDE **Restricted benefit** For pain where aspirin and/or paracetamol alone are inappropriate or have failed.								
5150C	Oral drops 100 mg per mL, 10 mL	‡1	..	..	13.71	14.80		Tramal	CS
	TRAMADOL HYDROCHLORIDE **Restricted benefit** Short-term treatment of acute pain.								
5231H	Injection 100 mg in 2 mL	5	..	..	13.10	14.19	[a]	Tramahexal	SZ
							[a]	Tramal 100	CS

Other analgesics and antipyretics

Salicylic acid and derivatives

	ASPIRIN								
5018D	Tablet 300 mg (dispersible)	96	..	..	8.50	9.59		Solprin	RC

Anilides

	PARACETAMOL								
3348F	Oral liquid 120 mg per 5 mL, 100 mL	‡1	..	..	9.38	10.47		Panamax	SW
3349G	Oral liquid 240 mg per 5 mL, 200 mL	‡1	..	..	10.68	11.77		Panamax 240 Elixir	SW
5196L	Tablet 500 mg	100	..	..	8.32	9.41	[a]	APO-Paracetamol	TX
							[a]	Chem mart Paracetamol	XS
							[a]	Febridol	GM
							[a]	Generic Health Pty Ltd	GQ
							[a]	Panamax	SW
							[a]	Paracetamol Sandoz	SZ
							[a]	Paralgin	FM
							[a]	Pharmacy Choice Paracetamol	YM
							[a]	Terry White Chemists Paracetamol	YS
	PARACETAMOL **Restricted benefit** Chronic arthropathies.								
5224Y	Tablet 500 mg	300	..	..	*12.12	13.21	[a]	APO-Paracetamol	TX
							[a]	Chem mart Paracetamol	XS
							[a]	Febridol	GM
							[a]	Generic Health Pty Ltd	GQ
							[a]	Panamax	SW
							[a]	Paracetamol Sandoz	SZ
							[a]	Paralgin	FM
							[a]	Pharmacy Choice Paracetamol	YM
							[a]	Terry White	YS

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
								Chemists	
								Paracetamol	

Antiepileptics

Antiepileptics

Carboxamide derivatives

CARBAMAZEPINE

5037D	Tablet 400 mg (controlled release)	200	..	..	49.02	35.40		Tegretol CR 400	NV
5038E	Tablet 200 mg (controlled release)	200	..	..	29.48	30.57		Tegretol CR 200	NV
5039F	Tablet 100 mg	200	..	[B]2.96	*21.46	19.59	[a]	Tegretol 100	NV
				..	18.51	19.60	[a]	Carbamazepine Sandoz	SZ
5040G	Tablet 200 mg	200	..	[B]2.96	*31.96	30.09	[a]	Tegretol 200	NV
				..	29.02	30.11	[a]	Carbamazepine Sandoz	SZ
							[a]	Teril	AF
5041H	Oral suspension 100 mg per 5 mL, 300 mL	‡1	..	..	21.35	22.44		Tegretol Liquid	NV

Anti-Parkinson drugs

Anticholinergic agents

Ethers of tropine or tropine derivatives

BENZTROPINE MESYLATE

5031T	Injection 2 mg in 2 mL	5	..	..	103.59	35.40		Cogentin	FK

Psycholeptics

Anxiolytics

Benzodiazepine derivatives

DIAZEPAM

5071X	Tablet 2 mg	50	..	..	7.72	8.81	[a]	Antenex 2	AF
							[a]	APO-Diazepam	TX
							[a]	Ranzepam	RA
							[a]	Valpam 2	QA
				[B]0.82	8.54	8.81	[a]	Valium	RO
5072Y	Tablet 5 mg	50	..	..	7.85	8.94	[a]	Antenex 5	AF
							[a]	APO-Diazepam	TX
							[a]	Diazepam-GA	GM
							[a]	Ranzepam	RA
							[a]	Valpam 5	QA
				[B]0.85	8.70	8.94	[a]	Valium	RO
5073B	Injection 10 mg in 2 mL	5	..	..	12.29	13.38		Hospira Pty Limited	HH

OXAZEPAM

5192G	Tablet 15 mg	25	..	..	7.65	8.74	[a]	Alepam 15	AF
				[B]2.69	10.34	8.74	[a]	Serepax	QA
5193H	Tablet 30 mg	25	..	..	7.65	8.74	[a]	Alepam 30	AF
							[a]	APO-Oxazepam	TX
							[a]	Murelax	FM
				[B]2.69	10.34	8.74	[a]	Serepax	QA

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Hypnotics and sedatives									
Benzodiazepine derivatives									
	NITRAZEPAM								
5189D	Tablet 5 mg	25	..	..	7.82	8.91	a	Alodorm	AF
				[B]1.45	9.27	8.91	a	Mogadon	VT
	TEMAZEPAM								
5221T	Tablet 10 mg	25	..	..	7.46	8.55	a	APO-Temazepam	TX
							a	Temaze	AF
							a	Temtabs	FM
				[B]1.21	8.67	8.55	a	Normison	QA

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Respiratory system							
	Drugs for obstructive airway diseases							
	Adrenergics for systemic use							
	Alpha- and beta-adrenoceptor agonists							
	ADRENALINE							
5004J	Injection 1 mg in 1 mL (1 in 1,000)	5	..	..	20.34	21.43	Link Medical Products Pty Ltd	LM

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Sensory organs							
	Ophthalmologicals							
	Antiinfectives							
	Antibiotics							
	CHLORAMPHENICOL							
5055C	Eye drops 5 mg per mL (0.5%), 10 mL	‡1	..	..	11.00	12.09	Chloromycetin	PF
							Chlorsig	QA

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
Various								
All other therapeutic products								
All other therapeutic products								
Antidotes								
	NALOXONE HYDROCHLORIDE							
5175J	Injection 2 mg in 5 mL	1	..	..	43.49	35.40	Naloxone Min-I-Jet	CS
All other non-therapeutic products								
All other non-therapeutic products								
Solvents and diluting agents, incl. irrigating solutions								
	SODIUM CHLORIDE							
5211G	Injection 9 mg per mL (0.9%), 10 mL	5	..	..	8.12	9.21	Pfizer Australia Pty Ltd	PF

Pharmaceutical Benefits for Optometrical Use

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Sensory organs							
	Ophthalmologicals							
	Antiinfectives							
	Antibiotics							
	CHLORAMPHENICOL							
5511C	Eye ointment 10 mg per g (1%), 4 g	‡1	..	..	9.76	10.85	Chloromycetin	PF
							Chlorsig	QA
5512D	Eye drops 5 mg per mL (0.5%), 10 mL	‡1	2	..	11.00	12.09	Chloromycetin	PF
							Chlorsig	QA
	GENTAMICIN SULFATE							
	Restricted benefit							
	Perioperative use in ophthalmic surgery;							
	Suspected pseudomonal eye infection.							
5566Y	Eye drops 3 mg (base) per mL (0.3%), 5 mL	‡1	2	..	18.29	19.38	Genoptic	AG
	TOBRAMYCIN							
	Restricted benefit							
	Perioperative use in ophthalmic surgery;							
	Suspected pseudomonal eye infection.							
5569D	Eye drops 3 mg per mL (0.3%), 5 mL	‡1	2	..	19.28	20.37	Tobrex	AQ
5570E	Eye ointment 3 mg per g (0.3%), 3.5 g	‡1	..	..	22.38	23.47	Tobrex	AQ
	Antivirals							
	ACICLOVIR							
	Restricted benefit							
	Herpes simplex keratitis.							
5501M	Eye ointment 30 mg per g (3%), 4.5 g	‡1	..	..	33.63	34.72	Zovirax	GK
	Other antiinfectives							
	CIPROFLOXACIN							
	Authority required							
	Bacterial keratitis under the supervision and direction of an ophthalmologist.							
5564W	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	..	*28.48	29.57 [a]	CiloQuin	IQ
				[B]2.06	*30.54	29.57 [a]	Ciloxan	AQ
	OFLOXACIN							
	Authority required							
	Bacterial keratitis under the supervision and direction of an ophthalmologist.							
5567B	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	..	*32.14	33.23	Ocuflox	AG
	Antiinflammatory agents							
	Corticosteroids, plain							
	DEXAMETHASONE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5565X	Eye drops 1 mg per mL (0.1%), 5 mL	‡1	..	..	10.61	11.70	Maxidex	AQ

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	FLUOROMETHOLONE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5513E	Eye drops 1 mg per mL (0.1%), 5 mL	‡1	..	..	10.61	11.70	Flucon	AQ
							FML Liquifilm	AG
	FLUOROMETHOLONE ACETATE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5533F	Eye drops 1 mg per mL (0.1%), 5 mL	‡1	..	..	10.61	11.70	Flarex	AQ
	HYDROCORTISONE ACETATE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5516H	Eye ointment 10 mg per g (1%), 5 g	‡1	..	..	12.69	13.78	Hycor	QA

Corticosteroids and mydriatics in combination

PREDNISOLONE ACETATE with PHENYLEPHRINE HYDROCHLORIDE
Restricted benefit
Uveitis.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

5568C	Eye drops 10 mg-1.2 mg per mL (1%-0.12%), 10 mL	‡1	..	..	23.73	24.82	Prednefrin Forte	AG

Antiinflammatory agents, non-steroids

FLURBIPROFEN SODIUM

5514F	Eye drops 300 micrograms per mL (0.03%), single dose units 0.4 mL, 5	1	..	..	16.82	17.91	Ocufen	AG

Antiglaucoma preparations and miotics

Sympathomimetics in glaucoma therapy

BRIMONIDINE TARTRATE

5534G	Eye drops 2 mg per mL (0.2%), 5 mL	‡1	5	..	20.14	21.23 [a]	Enidin	PE
				[B]1.63	21.77	21.23 [a]	Alphagan	AG
5563T	Eye drops 1.5 mg per mL (0.15%), 5 mL	‡1	5	..	20.14	21.23	Alphagan P 1.5	AG

BRIMONIDINE TARTRATE with TIMOLOL MALEATE
Restricted benefit
Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;

Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.

5535H	Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL	‡1	5	..	26.03	27.12	Combigan	AG

Parasympathomimetics

PILOCARPINE HYDROCHLORIDE

5536J	Eye drops 10 mg per mL (1%), 15 mL	‡1	5	..	12.53	13.62	Isopto Carpine	AQ
5537K	Eye drops 20 mg per mL (2%), 15 mL	‡1	5	..	13.78	14.87	Isopto Carpine	AQ
5538L	Eye drops 40 mg per mL (4%), 15 mL	‡1	5	..	16.63	17.72	Isopto Carpine	AQ

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Carbonic anhydrase inhibitors								
	BRINZOLAMIDE								
5540N	Eye drops 10 mg per mL (1%), 5 mL	‡1	5	..	22.77	23.86	a	BrinzoQuin	IQ
				[B]1.18	23.95	23.86	a	Azopt	AQ
	BRINZOLAMIDE with TIMOLOL MALEATE								
	Restricted benefit								
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;								
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.								
5562R	Eye drops 10 mg-5 mg (base) per mL (1%-0.5%), 5 mL	‡1	5	..	26.88	27.97		Azarga	AQ
	DORZOLAMIDE HYDROCHLORIDE								
5541P	Eye drops 20 mg (base) per mL (2%), 5 mL	‡1	5	..	21.29	22.38		Trusopt	MK
	DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE								
	Restricted benefit								
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;								
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.								
5542Q	Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL	‡1	5	..	27.18	28.27		Cosopt	MK
	Beta blocking agents								
	BETAXOLOL HYDROCHLORIDE								
5543R	Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL	‡1	5	..	14.77	15.86		Betoptic S	AQ
5544T	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	‡1	5	..	14.77	15.86	a	BetoQuin	IQ
				[B]2.09	16.86	15.86	a	Betoptic	AQ
	TIMOLOL MALEATE								
5546X	Eye gel 1 mg (base) per g (0.1%), 5 g	‡1	5	..	12.87	13.96		Nyogel	NV
5547Y	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	‡1	5	..	11.54	12.63	a	Tenopt	QA
				[B]3.03	14.57	12.63	a	Timoptol	FR
5548B	Eye drops 5 mg (base) per mL (0.5%), 5 mL	‡1	5	..	12.31	13.40	a	Tenopt	QA
				[B]3.03	15.34	13.40	a	Timoptol	FR
5549C	Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL	‡1	5	..	11.54	12.63		Timoptol XE	MK
5550D	Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL	‡1	5	..	12.31	13.40		Timoptol XE	MK
	Prostaglandin analogues								
	BIMATOPROST								
5551E	Eye drops 300 micrograms per mL (0.03%), 3 mL	‡1	5	..	42.14	35.40		Lumigan	AG
	BIMATOPROST with TIMOLOL MALEATE								
	Restricted benefit								
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;								
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.								
5558M	Eye drops 300 micrograms-5 mg (base) per mL (0.03%-0.5%), 3 mL	‡1	5	..	46.59	35.40		Ganfort 0.3/5	AG

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	LATANOPROST								
5552F	Eye drops 50 micrograms per mL (0.005%), 2.5 mL	‡1	5	..	42.14	35.40		Xalatan	PF
	LATANOPROST with TIMOLOL MALEATE								
	Restricted benefit								
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;								
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.								
5553G	Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL	‡1	5	..	46.59	35.40		Xalacom	PF
	TRAVOPROST								
5554H	Eye drops 40 micrograms per mL (0.004%), 2.5 mL	‡1	5	..	42.14	35.40		Travatan	AQ
	TRAVOPROST with TIMOLOL MALEATE								
	Restricted benefit								
	Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy;								
	Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy.								
5555J	Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL	‡1	5	..	46.59	35.40		Duotrav	AQ

Decongestants and antiallergics

Other antiallergics

	SODIUM CROMOGLYCATE								
	Restricted benefit								
	Vernal kerato-conjunctivitis.								
5529B	Eye drops 20 mg per mL (2%), 10 mL	‡1	5	..	14.21	15.30	[a]	Cromolux	AE
							[a]	Opticrom	SW

Other ophthalmologicals

Other ophthalmologicals

	CARBOMER								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
5503P	Eye gel 2 mg per g (0.2%), 10 g	‡1	5	..	10.27	11.36		GelTears	BU
							[a]	PAA	NM
				[B]1.50	11.77	11.36	[a]	Viscotears	NV
	CARBOMER								
	Authority required								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
5504Q	Eye gel 2 mg per g (0.2%), single dose units 0.6 mL, 30	3	5	..	*36.09	35.40		Viscotears Gel PF	NV
	CARBOMER 974								
	Authority required								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
5502N	Ocular lubricating gel 3 mg per g (0.3%), single dose units 0.5 g, 30	3	5	..	*36.06	35.40		Poly Gel	AQ

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	CARMELLOSE SODIUM **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome.								
5507W	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	5	..	10.59	11.68		Refresh Tears Plus	AG
5508X	Eye drops 10 mg per mL (1%), 15 mL	‡1	5	..	10.59	11.68		Refresh Liquigel	AG
	CARMELLOSE SODIUM **Authority required** Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
5505R	Eye drops 10 mg per mL (1%), single dose units 0.4 mL, 30	3	5	..	*36.06	35.40		Celluvisc	AG
5506T	Eye drops 5 mg per mL (0.5%), single dose units 0.4 mL, 30	3	5	..	*36.06	35.40		Cellufresh	AG
5509Y	Eye drops 2.5 mg per mL (0.25%), single dose units 0.6 mL, 24	4	5	..	*40.42	35.40		TheraTears	CX
5510B	Ocular lubricating gel 10 mg per mL (1%), single dose units 0.6 mL, 28	3	5	..	*34.08	35.17		TheraTears	CX
	CARMELLOSE SODIUM with GLYCERIN **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome. **Note** The in-use shelf life of Optive is 6 months from the date of opening.								
5556K	Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL	‡1	3	..	10.59	11.68		Optive	AG
	CARMELLOSE SODIUM with GLYCERIN **Authority required** Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
5561Q	Eye drops 5 mg-9 mg per mL (0.5%-0.9%), single dose units 0.4 mL, 30	3	5	..	*36.06	35.40		Optive	AG
	HYPROMELLOSE **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome.								
5517J	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	5	..	10.27	11.36		Methopt	QA
5518K	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	‡1	5	..	10.27	11.36	[a]	In a Wink Moisturising	NM
				[B]1.95	12.22	11.36	[a]	Genteal	NV
	HYPROMELLOSE with CARBOMER 980 **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome.								
5519L	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	‡1	5	..	10.27	11.36	[a]	HPMC PAA	NM
				[B]1.95	12.22	11.36	[a]	Genteal gel	NV
	HYPROMELLOSE with DEXTRAN **Restricted benefit** Severe dry eye syndrome, including Sjogren's syndrome.								
5520M	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	‡1	5	..	10.49	11.58	[a]	Poly-Tears	IQ
				[B]1.77	12.26	11.58	[a]	Tears Naturale	AQ

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	HYPROMELLOSE with DEXTRAN								
	Authority required								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
5521N	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28	3	5	..	*35.07	35.40		Bion Tears	AQ
	PARAFFIN								
5522P	Pack containing 2 tubes compound eye ointment 3.5 g	‡1	5	..	20.60	21.69		Poly Visc	IQ
							[a]	Ircal	PE
				[B]2.12	22.72	21.69	[a]	Lacri-Lube	AG
5523Q	Compound eye ointment 3.5 g	2	5	..	*21.24	22.33	[a]	Poly Visc	IQ
				[B]2.18	*23.42	22.33	[a]	Duratears	AQ
	POLYETHYLENE GLYCOL 400								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
	Note								
	The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening.								
5559N	Eye drops 2.5 mg per mL (0.25%), 15 mL	‡1	5	..	10.59	11.68		Blink Intensive Tears	AO
	POLYETHYLENE GLYCOL 400								
	Authority required								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
5560P	Eye drops 2.5 mg per mL (0.25%), single dose units 0.4 mL, 20	5	5	..	*39.37	35.40		Blink Intensive Tears	AO
	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
5524R	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL	‡1	5	..	10.59	11.68		Systane	AQ
	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
	Authority required								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
5532E	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28	2	5	..	*34.08	35.17		Systane	AQ
	POLYVINYL ALCOHOL								
	Restricted benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
5525T	Eye drops 30 mg per mL (3%), 15 mL	‡1	5	..	10.27	11.36	[a]	PVA Forte	PE
				[B]5.59	15.86	11.36	[a]	Liquifilm Forte	AG
5526W	Eye drops 14 mg per mL (1.4%), 15 mL	‡1	5	..	10.27	11.36	[a]	PVA Tears	PE
				[B]1.60	11.87	11.36	[a]	Liquifilm Tears	AG
5527X	Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡1	5	..	10.27	11.36		Vistil	AE
5528Y	Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as	‡1	5	..	10.27	11.36		Vistil Forte	AE

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	preservative)							
	SOY LECITHIN							
	Authority required							
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.							
5545W	Eye spray 10 mg per mL (1%), 10 mL	2	5	..	*36.06	35.40	tearsagain	RB

Ophthalmological and otological preparations

Antiinfectives

Antiinfectives

	FRAMYCETIN SULFATE							
5557L	Eye and ear drops 5 mg per mL (0.5%), 8 mL	‡1	2	..	10.11	11.20	Soframycin	SW

Items Available under Special Arrangements (Section 100)

Section 100 – Items Available under Special Arrangement

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in this Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate.

These alternative arrangements are provided for under section 100 of the National Health Act 1953. Several programs exist for the provision of drugs as pharmaceutical benefits in this way and this section lists those drugs which are available under the following programs:

- **Highly Specialised Drugs Program**
- **Botulinum Toxin Program**
- **Human Growth Hormone Program**
- **IVF/GIFT Program**
- **Opiate Dependence Treatment Program**

Complete details concerning the availability of drugs as benefits under these programs may be obtained by telephoning the relevant contact number(s) shown in each section, or in certain cases, by referring to the telephone number provided for individual drugs listings.

Section 100 – Highly Specialised Drugs Program

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement – Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Private Hospitals – **In addition to the above requirements**, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval of authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia, or by using Medicare Australia's Authority Freecall service (1800 888 333). **Prescribers must quote the provider number of the hospital when applying**. Not more than two months' supply (one month's supply in the case of Clozapine), with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital's dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready- prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than $40;
- $4 for drugs with a price ex-manufacturer of between $40 and $100;
- 4% for drugs with a price ex-manufacturer of between $100.01 and $1000;
- $40 for drugs with a price ex-manufacturer of greater than $1000.

Public Hospitals – For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies.

If you would like further information about the Highly Specialised Drugs Program, please contact your pharmacy, Medicare Australia (Ph: 132 290) or the Australian Government adviser, the Highly Specialised Drugs Working Party Secretariat (Ph: (02) 6289 2331).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Blood and blood forming organs

Antihemorrhagics

Vitamin K and other hemostatics

Other systemic hemostatics

ELTROMBOPAG

Note

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:
(1) Splenectomised and:
(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
OR
(2) Not splenectomised and:
(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L;
OR
(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

Authority required

Initial (grandfather patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Note
No applications for increased repeats will be authorised.

Authority required
Continuing therapy or re-initiation after a break in therapy
First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Note
No applications for increased repeats will be authorised.

Authority required
Second and subsequent applications for continuing therapy
Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
No applications for increased repeats will be authorised.

5827Q	Tablet 25 mg (as olamine)	28	5	..	1558.42	Revolade	GK
5828R	Tablet 50 mg (as olamine)	28	5	..	3070.42	Revolade	GK

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

ROMIPLOSTIM

Note

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:
(1) Splenectomised and:
(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
OR
(2) Not splenectomised and:
(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L;
OR
(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Authority required

Initial (grandfather patients)
Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required
Continuing therapy or re-initiation after a break in therapy
First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required
Second and subsequent applications for continuing therapy
Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

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	AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses of higher than 10 micrograms/kg/week. **Note** Special Pricing Arrangements apply.						
9697J	Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted)	1	..	..	1023.02	Nplate	AN
9699L	Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted)	1	..	..	2001.42	Nplate	AN

Antianemic preparations

Other antianemic preparations

Other antianemic preparations

DARBEPOETIN ALFA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

6320P	Injection 10 micrograms in 0.4 mL pre-filled syringe	8	5	..	*376.74	Aranesp	AN
6321Q	Injection 20 micrograms in 0.5 mL pre-filled syringe	8	5	..	*703.86	Aranesp	AN
6322R	Injection 30 micrograms in 0.3 mL pre-filled syringe	8	5	..	*960.58	Aranesp	AN
6323T	Injection 40 micrograms in 0.4 mL pre-filled syringe	8	5	..	*1160.02	Aranesp	AN
6324W	Injection 50 micrograms in 0.5 mL pre-filled syringe	8	5	..	*1423.20	Aranesp	AN
6325X	Injection 60 micrograms in 0.3 mL pre-filled syringe	8	5	..	*1663.08	Aranesp	AN
6326Y	Injection 100 micrograms in 0.5 mL pre-filled syringe	8	5	..	*2666.92	Aranesp	AN
6365B	Injection 150 micrograms in 0.3 mL pre-filled syringe	8	5	..	*3950.92	Aranesp	AN
6438W	Injection 80 micrograms in 0.4 mL pre-filled syringe	8	5	..	*2174.42	Aranesp	AN
6488L	Injection 20 micrograms in 0.5 mL pre-filled injection pen	8	5	..	*703.86	Aranesp SureClick	AN
6489M	Injection 40 micrograms in 0.4 mL pre-filled injection pen	8	5	..	*1160.02	Aranesp SureClick	AN
6490N	Injection 60 micrograms in 0.3 mL pre-filled injection pen	8	5	..	*1663.06	Aranesp SureClick	AN
6491P	Injection 80 micrograms in 0.4 mL pre-filled injection pen	8	5	..	*2174.42	Aranesp SureClick	AN
6492Q	Injection 100 micrograms in 0.5 mL pre-filled injection pen	8	5	..	*2666.90	Aranesp SureClick	AN
6493R	Injection 150 micrograms in 0.3 mL pre-filled injection pen	8	5	..	*3950.90	Aranesp SureClick	AN

EPOETIN ALFA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

6204M	Injection 2,000 units in 0.5 mL pre-filled syringe	12	5	..	*543.90	Eprex 2000	JC
6205N	Injection 3,000 units in 0.3 mL pre-filled syringe	12	5	..	*700.00	Eprex 3000	JC
6206P	Injection 4,000 units in 0.4 mL pre-filled syringe	12	5	..	*889.70	Eprex 4000	JC
6207Q	Injection 10,000 units in 1 mL pre-filled syringe	12	5	..	*2016.72	Eprex 10000	JC
6251B	Injection 1,000 units in 0.5 mL pre-filled syringe	12	5	..	*296.90	Eprex 1000	JC
6302Q	Injection 5,000 units in 0.5 mL pre-filled syringe	12	5	..	*1103.76	Eprex 5000	JC

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
6303R	Injection 6,000 units in 0.6 mL pre-filled syringe	12	5	..	*1301.56	Eprex 6000	JC
6305W	Injection 8,000 units in 0.8 mL pre-filled syringe	12	5	..	*1674.34	Eprex 8000	JC
6339P	Injection 40,000 units in 1 mL pre-filled syringe	2	5	..	*1300.42	Eprex 40,000	JC
6434P	Injection 20,000 units in 0.5 mL pre-filled syringe	12	5	..	*3922.42	Eprex 20,000	JC
	EPOETIN BETA						
	Authority required						
	Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.						
6480C	Injection 2,000 units in 0.3 mL pre-filled syringe	12	5	..	*543.90	NeoRecormon	RO
6481D	Injection 3,000 units in 0.3 mL pre-filled syringe	12	5	..	*700.00	NeoRecormon	RO
6482E	Injection 4,000 units in 0.3 mL pre-filled syringe	12	5	..	*889.70	NeoRecormon	RO
6483F	Injection 5,000 units in 0.3 mL pre-filled syringe	12	5	..	*1103.78	NeoRecormon	RO
6484G	Injection 6,000 units in 0.3 mL pre-filled syringe	12	5	..	*1301.56	NeoRecormon	RO
6485H	Injection 10,000 units in 0.6 mL pre-filled syringe	12	5	..	*2016.72	NeoRecormon	RO
6486J	Injection 20,000 units in 0.6 mL pre-filled syringe	12	5	..	*3922.42	NeoRecormon	RO
	EPOETIN LAMBDA						
	Note						
	Epoetin lambda should only be administered by the intravenous route.						
	Authority required						
	Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.						
9588P	Injection 5,000 units in 0.5 mL pre-filled syringe	12	5	..	*1048.12	Novicrit	NV
9590R	Injection 6,000 units in 0.6 mL pre-filled syringe	12	5	..	*1235.50	Novicrit	NV
9593X	Injection 8,000 units in 0.8 mL pre-filled syringe	12	5	..	*1588.66	Novicrit	NV
9595B	Injection 10,000 units in 1 mL pre-filled syringe	12	5	..	*1913.02	Novicrit	NV
9685R	Injection 1,000 units in 0.5 mL pre-filled syringe	12	5	..	*281.60	Novicrit	NV
9686T	Injection 2,000 units in 1 mL pre-filled syringe	12	5	..	*515.60	Novicrit	NV
9687W	Injection 3,000 units in 0.3 mL pre-filled syringe	12	5	..	*663.50	Novicrit	NV
9688X	Injection 4,000 units in 0.4 mL pre-filled syringe	12	5	..	*843.20	Novicrit	NV
	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA						
	Authority required						
	Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.						
9574X	Injection 30 micrograms in 0.3 mL pre-filled syringe	2	5	..	*390.36	Mircera	RO
9575Y	Injection 50 micrograms in 0.3 mL pre-filled syringe	2	5	..	*646.34	Mircera	RO
9576B	Injection 75 micrograms in 0.3 mL pre-filled syringe	2	5	..	*938.28	Mircera	RO
9577C	Injection 100 micrograms in 0.3 mL pre-filled syringe	2	5	..	*1205.24	Mircera	RO
9578D	Injection 120 micrograms in 0.3 mL pre-filled syringe	2	5	..	*1388.06	Mircera	RO
9579E	Injection 200 micrograms in 0.3 mL pre-filled syringe	2	5	..	*1970.72	Mircera	RO
9580F	Injection 360 micrograms in 0.6 mL pre-filled syringe	2	5	..	*3372.94	Mircera	RO

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Cardiovascular system

Antihypertensives

Other antihypertensives

Other antihypertensives

AMBRISENTAN

Caution

Ambrisentan is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

Note

Any queries concerning the arrangements to prescribe ambrisentan may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

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Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

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Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(c) WHO Functional Class IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (change or re-commencement for all patients)
Application for initial treatment with ambrisentan of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised ambrisentan after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with ambrisentan; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than ambrisentan.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with ambrisentan of patients who have received approval for initial PBS-subsidised treatment with ambrisentan and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of ambrisentan treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Special Pricing Arrangements apply.

9648T	Tablet 5 mg	30	..	..	4081.42	Volibris	GK
9649W	Tablet 10 mg	30	..	..	4081.42	Volibris	GK

BOSENTAN MONOHYDRATE

Caution

Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

Note

Any queries concerning the arrangements to prescribe bosentan monohydrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.
All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(c) WHO Functional Class IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(e) WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Applications for authorisation must be in writing and must include:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients)
Application for initial treatment with bosentan monohydrate of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than bosentan monohydrate.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Authority required** Cessation of treatment (all patients) Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to connective tissue disease or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment. Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements]. Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month. **Note** Special Pricing Arrangements apply.						
6429J	Tablet 62.5 mg (base)	60	..	..	4081.42	Tracleer	AT
6430K	Tablet 125 mg (base)	60	..	..	4081.42	Tracleer	AT

EPOPROSTENOL SODIUM

Note

Any queries concerning the arrangements to prescribe epoprostenol sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class IV primary pulmonary hypertension; OR
(b) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
(5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
5036C	Powder for I.V. infusion 500 micrograms (base) infusion administration set	1	..	..	50.00	Flolan Kit	GK
5042J	Powder for I.V. infusion 1.5 mg (base) infusion administration set	1	..	..	89.65	Flolan Kit	GK

ILOPROST TROMETAMOL

Note

Any queries concerning the arrangements to prescribe iloprost trometamol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with iloprost and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class IV primary pulmonary hypertension; OR
(c) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
(d) WHO Functional Class IV drug-induced pulmonary arterial hypertension.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (change or re-commencement for all patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR
(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than iloprost trometamol; OR
(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
(5) for WHO Functional Class III patients, where this is the first application for iloprost trometamol, assessment details of the PBS-subsidised PAH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Special Pricing Arrangements apply.

6456T	Solution for inhalation 20 micrograms (base) in 2 mL	30	..	..	1122.42	Ventavis	BN

SILDENAFIL CITRATE

Note

Any queries concerning the arrangements to prescribe sildenafil citrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

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The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.
All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	particular test/s could not be conducted must be provided with the authority application [see Note for test requirements]. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Authority required** Initial (change or re-commencement for all patients) Application for initial PBS-subsidised treatment with sildenafil citrate of patients with one of the following: (a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; OR (b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than sildenafil citrate. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and (3) the date of the first application for PBS-subsidised treatment with a PAH agent; and (4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements]. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Authority required** Continuing treatment (all patients) Continuing PBS-subsidised treatment with sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sildenafil citrate treatment [see Note for definition of response]. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6MWT. The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
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TADALAFIL

Note

Any queries concerning the arrangements to prescribe tadalafil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.
All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO;

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (change or re-commencement for all patients)
Application for initial treatment with tadalafil of patients with one of the following:
(a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised tadalafil after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with tadalafil; OR
(b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than tadalafil.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Continuing treatment (all patients)
Continuing PBS-subsidised treatment with tadalafil of patients who have received approval for initial PBS-subsidised treatment with tadalafil, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of tadalafil treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
1304P	Tablet 20 mg	56	..	..	878.49	Adcirca	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	

Systemic hormonal preparations, excl. sex hormones and insulins

Pituitary and hypothalamic hormones and analogues

Hypothalamic hormones

Somatostatin and anaolgues

LANREOTIDE ACETATE

Authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment.

6332G	Powder for suspension for injection 30 mg (base) with diluent ampoule	2	11	..	*1546.42		Somatuline LA	IS

LANREOTIDE ACETATE

Authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment;

Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6423C	Injection 60 mg (base) in single dose pre-filled syringe	2	11	..	*2736.42		Somatuline Autogel	IS
6424D	Injection 90 mg (base) in single dose pre-filled syringe	2	11	..	*3626.42		Somatuline Autogel	IS
6425E	Injection 120 mg (base) in single dose pre-filled syringe	2	11	..	*4526.42		Somatuline Autogel	IS

OCTREOTIDE

Authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily;

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6227R	Injection 50 micrograms (as acetate) in 1 mL	90	11	..	*650.28	[a]	Hospira Pty Limited	HH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
						[a] Octreotide MaxRx	XF
						[a] Sandostatin 0.05	NV
6228T	Injection 100 micrograms (as acetate) in 1 mL	90	11	..	*1282.80	[a] Hospira Pty Limited	HH
						[a] Octreotide MaxRx	XF
						[a] Sandostatin 0.1	NV
6229W	Injection 500 micrograms (as acetate) in 1 mL	90	11	..	*6240.90	[a] Hospira Pty Limited	HH
						[a] Octreotide MaxRx	XF
						[a] Sandostatin 0.5	NV

OCTREOTIDE

Authority required

Acromegaly in a patient controlled on Sandostatin subcutaneous injections.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months of treatment;

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections.
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6426F	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	1	11	..	1353.28	Sandostatin LAR	NV
6427G	Injection (modified release) 20 mg (as acetate), vial and diluent syringe	1	11	..	1786.23	Sandostatin LAR	NV
6428H	Injection (modified release) 30 mg (as acetate), vial and diluent syringe	1	11	..	2223.88	Sandostatin LAR	NV

Calcium homeostasis

Anti-parathyroid agents

Other anti-parathyroid agents

CINACALCET

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy.

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment.

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.						
	Note Special Pricing Arrangements apply.						
9625N	Tablet 30 mg (as hydrochloride)	56	5	..	*623.88	Sensipar	AN
9626P	Tablet 60 mg (as hydrochloride)	56	5	..	*1233.86	Sensipar	AN
9627Q	Tablet 90 mg (as hydrochloride)	56	5	..	*1827.58	Sensipar	AN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Antiinfectives for systemic use

Antibacterials for systemic use

Macrolides, lincosamides and streptogramins

Macrolides

AZITHROMYCIN

Authority required

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

6221K	Tablet 600 mg (as dihydrate)	16	5	..	*124.94	Zithromax	PF

CLARITHROMYCIN

Authority required

Treatment of Mycobacterium avium complex infections.

6151R	Tablet 250 mg	100	2	..	36.90	Klacid	AB
6152T	Tablet 500 mg	100	2	..	65.74	Klacid	AB

Antimycobacterials

Drugs for treatment of tuberculosis

Antibiotics

RIFABUTIN

Authority required

Treatment of Mycobacterium avium complex infections in HIV-positive patients;

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

6195C	Capsule 150 mg	120	5	..	*617.94	Mycobutin	PF

Antivirals for systemic use

Direct acting antivirals

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

CIDOFOVIR

Authority required

Treatment of cytomegalovirus retinitis in patients with AIDS.

6247T	Solution for I.V. infusion 375 mg (anhydrous) in 5 mL single use vial	4	3	..	*3646.42	Vistide	GI

GANCICLOVIR

Authority required

Cytomegalovirus retinitis in severely immunocompromised patients;

Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease;

Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease.

6136Y	Powder for I.V. infusion 500 mg (as sodium)	10	1	..	*588.82	Cymevene	RO

VALACICLOVIR

Authority required

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.

6280M	Tablet 500 mg (as hydrochloride)	500	2	..	*2162.32	[a] APO-Valaciclovir	TX
						[a] Valaciclovir RBX	RA
						[a] Valtrex	GK
						[a] Valvala	NV

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
					[a]	Zelitrex	GM

VALGANCICLOVIR HYDROCHLORIDE
Authority required
Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome;

Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease.

6357N	Tablet 450 mg (base)	120	5	..	*4538.02	Valcyte	RO
9675F	Powder for oral solution 50 mg (base) per mL, 100 mL	11	5	..	*#4623.83	Valcyte	RO

Phosphonic acid derivatives

FOSCARNET SODIUM
Authority required
Treatment of cytomegalovirus retinitis in patients with AIDS;

Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection.

6134W	I.V. infusion 24 mg per mL, 250 mL	6	1	..	1223.92	Foscavir	IX

Protease inhibitors

ATAZANAVIR
Authority required
Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

6451M	Capsule 150 mg (as sulfate)	120	5	..	*1090.24	Reyataz	BQ
6452N	Capsule 200 mg (as sulfate)	120	5	..	*1438.18	Reyataz	BQ
9614B	Capsule 300 mg (as sulfate)	60	5	..	*1090.24	Reyataz	BQ
9646Q	Capsule 100 mg (as sulfate)	120	5	..	*730.14	Reyataz	BQ

DARUNAVIR
Authority required
Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance, and who has not demonstrated darunavir resistance associated mutations detected on resistance testing.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

5823L	Tablet 400 mg (as ethanolate)	120	5	..	*1444.70	Prezista	JC

DARUNAVIR
Authority required
Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

5000E	Tablet 600 mg (as ethanolate)	120	5	..	*2143.84	Prezista	JC
9581G	Tablet 150 mg (as ethanolate)	240	5	..	1095.13	Prezista	JC

FOSAMPRENAVIR
Authority required
Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
6453P	Tablet 700 mg (as calcium)	120	5	..	*795.08	Telzir	VI
6454Q	Oral liquid 50 mg (as calcium) per mL, 225 mL	8	5	..	*851.38	Telzir	VI
	INDINAVIR **Authority required** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6202K	Capsule 400 mg (as sulfate)	360	5	..	*952.82	Crixivan 400 mg	MK
	RITONAVIR **Authority required** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6494T	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	10	5	..	*952.82	Norvir	AB
9677H	Tablet 100 mg	720	5	..	*1028.58	Norvir	AB
	SAQUINAVIR **Authority required** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6498B	Tablet 500 mg (as mesylate)	240	5	..	*1057.54	Invirase	RO
	TIPRANAVIR **Authority required** Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. **Note** Special Pricing Arrangements apply.						
9610T	Capsule 250 mg	240	5	..	*2188.42	Aptivus	BY
	TIPRANAVIR **Authority required** Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with ritonavir in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. **Note** Special Pricing Arrangements apply.						
9676G	Oral liquid 100 mg per mL, 95 mL	7	5	..	*2420.44	Aptivus	BY

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Nucleoside and nucleotide reverse transcriptase inhibitors						
	ABACAVIR						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6264Q	Tablet 300 mg (as sulfate)	120	5	..	*592.98	Ziagen	VI
6265R	Oral solution 20 mg (as sulfate) per mL, 240 mL	8	5	..	*689.86	Ziagen	VI
	ADEFOVIR DIPIVOXIL						
	Authority required						
	Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;						
	Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
	Note						
	Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
6450L	Tablet 10 mg	60	5	..	*1296.42	Hepsera	GI
	DIDANOSINE						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6298L	Capsule 125 mg (containing enteric coated beadlets)	60	5	..	*298.52	Videx EC	BQ
6299M	Capsule 200 mg (containing enteric coated beadlets)	60	5	..	*346.30	Videx EC	BQ
6300N	Capsule 250 mg (containing enteric coated beadlets)	60	5	..	*431.24	Videx EC	BQ
6301P	Capsule 400 mg (containing enteric coated beadlets)	60	5	..	*686.14	Videx EC	BQ
	EMTRICITABINE						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6137B	Capsule 200 mg	60	5	..	*592.98	Emtriva	GI
	ENTECAVIR MONOHYDRATE						
	Authority required						
	Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy;						
	Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Note						
	PBS-subsidised entecavir monohydrate must be used as monotherapy.						
9602J	Tablet 0.5 mg	60	5	..	*805.76	Baraclude	BQ
	ENTECAVIR MONOHYDRATE						
	Authority required						
	Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance; Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
	Note						
	PBS-subsidised entecavir monohydrate must be used as monotherapy.						
9603K	Tablet 1 mg	60	5	..	*1296.42	Baraclude	BQ
	LAMIVUDINE						
	Authority required						
	Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
6257H	Tablet 100 mg	56	5	..	*317.08	Zeffix	GK
6271C	Oral solution 5 mg per mL, 240 mL	5	5	..	*369.97	Zeffix	GK
	LAMIVUDINE						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6193Y	Tablet 150 mg	120	5	..	*592.98	3TC	VI
6194B	Oral solution 10 mg per mL, 240 mL	8	5	..	*725.94	3TC	VI
6435Q	Tablet 300 mg	60	5	..	*592.98	3TC	VI
	STAVUDINE						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6186N	Capsule 20 mg	120	5	..	*588.82	Zerit	BQ
6189R	Capsule 30 mg	120	5	..	*700.48	Zerit	BQ
6190T	Capsule 40 mg	120	5	..	*931.82	Zerit	BQ

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	TELBIVUDINE						
	Authority required						
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
9630W	Tablet 600 mg	56	5	..	*528.26	Sebivo	NV
	TENOFOVIR						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
	Authority required						
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
	Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
	Authority required Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance; Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
	Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
6358P	Tablet containing tenofovir disoproxil fumarate 300 mg	60	5	..	*1011.26	Viread	GI
	ZIDOVUDINE						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6153W	Capsule 100 mg	400	5	..	*861.14	Retrovir	GK
6154X	Capsule 250 mg	240	5	..	*1279.18	Retrovir	GK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
6155Y	Syrup 10 mg per mL, 200 mL	15	5	..	*706.62	Retrovir	GK

Non-nucleoside reverse transcriptase inhibitors

EFAVIRENZ

Authority required

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

6356M	Tablet 600 mg	60	5	..	*571.30	Stocrin	MK
6372J	Oral solution 30 mg per mL, 180 mL	7	5	..	*599.53	Stocrin	MK
9618F	Tablet 200 mg	180	5	..	*571.30	Stocrin	MK

ETRAVIRINE

Authority required

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

5062K	Tablet 200 mg	120	5	..	*1279.42	Intelence	JC

NEVIRAPINE

Authority required

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

6215D	Tablet 200 mg	120	5	..	*571.30	Viramune	BY
9571R	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	10	5	..	*1396.42	Viramune	BY

NEVIRAPINE

Authority required

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient who has been stabilised on nevirapine immediate release with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

1129K	Tablet 400 mg (extended release)	60	5	..	*571.30	Viramune XR	BY

RILPIVIRINE

Authority required

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

1170N	Tablet 25 mg (as hydrochloride)	60	5	..	*571.30	Edurant	JC

Antivirals for treatment of HIV infections, combinations

ABACAVIR with LAMIVUDINE

Authority required

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection.						
6458X	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	60	5	..	*1174.42	Kivexa	VI
	ABACAVIR with LAMIVUDINE and ZIDOVUDINE						
	Authority required						
	Initial treatment of HIV infection in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection.						
6327B	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	120	5	..	*1750.42	Trizivir	VI
	LAMIVUDINE with ZIDOVUDINE						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6234D	Tablet 150 mg-300 mg	120	5	..	*1203.62	Combivir	VI
	LOPINAVIR with RITONAVIR						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6341R	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	10	5	..	*1336.42	Kaletra	AB
6495W	Tablet 200 mg-50 mg	240	5	..	*1416.42	Kaletra	AB
9633B	Tablet 100 mg-25 mg	120	5	..	*362.62	Kaletra	AB
	TENOFOVIR with EMTRICITABINE						
	Authority required						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
6468K	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	60	5	..	*1576.62	Truvada	GI
	TENOFOVIR with EMTRICITABINE and EFAVIRENZ						
	Authority required						
	Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection.						
9650X	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	60	5	..	*2119.78	Atripla	GI
	TENOFOVIR with EMTRICITABINE and RILPIVIRINE						
	Authority required						
	Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection.						
1490K	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride)	60	5	..	*2119.78	Eviplera	GI

Other antivirals

ENFUVIRTIDE

Authority required

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
6455R	Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)	2	5	..	*4472.42	Fuzeon	RO

MARAVIROC

Authority required

Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

9572T	Tablet 150 mg	120	5	..	*1881.82	Celsentri	VI
9573W	Tablet 300 mg	120	5	..	*1881.82	Celsentri	VI

RALTEGRAVIR

Authority required

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

9629T	Tablet 400 mg (as potassium)	120	5	..	*1377.52	Isentress	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Antineoplastic and immunomodulating agents

Antineoplastic agents

Antimetabolites

Pyrimidine analogues

AZACITIDINE

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial PBS-subsidised treatment of a patient with:
(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:
1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
(d) a copy of the full blood examination report; and
(e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
(f) a signed patient acknowledgment form.

No more than three cycles will be authorised.

Note

Special Pricing Arrangements apply.

6100C	Powder for injection 100 mg	14	2	..	*7746.46	Vidaza	CJ

AZACITIDINE

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required
Continuing treatment of a patient with:
(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification;
who has previously been issued with an authority prescription for azacitidine and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Up to six cycles will be authorised.

Note
Special Pricing Arrangements apply.

6138C	Powder for injection 100 mg	14	5	..	*7746.46	Vidaza	CJ

Cytotoxic antibiotics and related substances
Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL
Authority required
Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement;

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement.

6249X	Suspension for I.V. infusion 20 mg in 10 mL	4	5	..	*2538.38	Caelyx	JC
						Lipodox	ZF

Immunostimulants

Immunostimulants
Colony stimulating factors

FILGRASTIM
Authority required
For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);						
	A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));						
	A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));						
	A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.						
	Authority required						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP).						
1082Y	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2561.96	TevaGrastim	AS
1113N	Injection 480 micrograms in 0.8 mL single use pre-filled syringe	20	11	..	*4079.00	TevaGrastim	AS
5830W	Injection 120 micrograms in 0.2 mL single use pre-filled syringe	20	11	..	*1052.64	Nivestim	HH
6126K	Injection 300 micrograms in 1 mL	20	11	..	*2561.96	Neupogen	AN
6127L	Injection 480 micrograms in 1.6 mL	20	11	..	*4079.00	Neupogen	AN
6291D	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2561.96	Neupogen	AN
6292E	Injection 480 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*4079.00	Neupogen	AN
9693E	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2561.96	Nivestim	HH
9695G	Injection 480 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*4079.00	Nivestim	HH
	LENOGRASTIM						
	Authority required						
	Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy;						
	Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors;						
	Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation;						
	Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.						
	Authority required						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma;						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade);						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma;						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease;						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.						
6337M	Powder for injection 13,400,000 i.u. (105 micrograms)	20	11	..	*1071.42	Granocyte 13	HH
6338N	Powder for injection 33,600,000 i.u. (263 micrograms)	20	11	..	*2613.62	Granocyte 34	HH
	PEGFILGRASTIM						
	Authority required						
	For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;						
	A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.						
	Authority required						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma;						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP).						
6363X	Injection 6 mg in 0.6 mL single use pre-filled syringe	1	11	..	1971.42	Neulasta	AN

Interferons

INTERFERON ALFA-2a

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
(2) Evidence of chronic liver injury as determined by:
(a) Confirmed elevated serum ALT; or
(b) Liver biopsy;

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

6210W	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*936.12	Roferon-A	RO
6211X	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1387.32	Roferon-A	RO
6212Y	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1833.72	Roferon-A	RO
6213B	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*2727.72	Roferon-A	RO

INTERFERON ALFA-2b

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
(2) Evidence of chronic liver injury as determined by:
(a) Confirmed elevated serum ALT; or
(b) Liver biopsy;

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

6218G	Solution for injection 18,000,000 i.u. in 3 mL single dose vial	15	5	..	*2727.57	Intron A	MK
6219H	Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial	15	5	..	*3770.22	Intron A	MK
6246R	Solution for injection 10,000,000 i.u. in 1 mL single dose vial	15	5	..	*1535.91	Intron A	MK
6253D	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*378.20	Intron A Redipen	MK
6254E	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*626.06	Intron A Redipen	MK
6255F	Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*1238.02	Intron A Redipen	MK

INTERFERON GAMMA-1b

Authority required

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

6148N	Injection 2,000,000 i.u. in 0.5 mL	12	11	..	*2768.22	Imukin	BY

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	PEGINTERFERON ALFA-2a						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	Authority required						
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B;						
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;						
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
6439X	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2378.22	Pegasys	RO
6449K	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2746.88	Pegasys	RO
	RIBAVIRIN and PEGINTERFERON ALFA-2a						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	Caution						
	Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.						
	Authority required						
	Patients naive to interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy. **Authority required** Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
6392K	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	2	5	..	*3119.26	Pegasys RBV	RO
6394M	Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	2	5	..	*3131.70	Pegasys RBV	RO
6395N	Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	2	5	..	*3292.24	Pegasys RBV	RO
6396P	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	2	5	..	*3452.78	Pegasys RBV	RO
	RIBAVIRIN and PEGINTERFERON ALFA-2b **Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. **Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment. **Authority required** Patients naive to interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients weighing at least 27 kg who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy. **Authority required** Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
6400W	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	2	5	..	*2166.16	Pegatron	MK
6401X	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	2	5	..	*2469.14	Pegatron	MK
6405D	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	2	5	..	*3146.04	Pegatron	MK

RIBAVIRIN and PEGINTERFERON ALFA-2b

Caution

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Caution

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Authority required

Patients naive to interferon based therapies (non-pegylated or pegylated)

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:
(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.
For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.
Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12).
Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy. **Authority required** Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
6402Y	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	2	5	..	*2754.08	Pegatron	MK
6407F	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent	2	5	..	*3538.00	Pegatron	MK
6409H	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	2	5	..	*4125.94	Pegatron	MK
6410J	Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	2	5	..	*4125.94	Pegatron	MK
9634C	Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	2	5	..	*4410.90	Pegatron	MK

Immunosuppressants

Immunosuppressants

Selective immunosuppressants

ABATACEPT

Note

Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

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Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.						
	Authority required Continuing treatment Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults: (a) who have a documented history of severe active rheumatoid arthritis; and (b) who have demonstrated an adequate response to treatment with abatacept; and (c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or — shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of 24 weeks of treatment will be approved under this restriction. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** Special Pricing Arrangements apply.						
9621J	Powder for I.V. infusion 250 mg	1	..	..	531.03	Orencia	BQ
	EVEROLIMUS **Caution** Careful monitoring of patients is mandatory. **Authority required** Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required; Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.						
6459Y	Tablet 0.25 mg	120	5	..	*506.24	Certican	NV
6460B	Tablet 0.5 mg	120	5	..	*1006.06	Certican	NV
6461C	Tablet 0.75 mg	240	5	..	*2930.02	Certican	NV
9582H	Tablet 1 mg	240	5	..	*3891.22	Certican	NV
	MYCOPHENOLATE MOFETIL **Caution** Careful monitoring of patients is mandatory.						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	
	Authority required Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required; Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.							
6208R	Capsule 250 mg	600	5	..	*977.28	a	APO-Mycophenolate	TX
						a	CellCept	RO
						a	Imulate	QA
						a	Mycophenolate Sandoz	SZ
						a	Pharmacor Mycophenolate 250	CR
				..	*977.34	a	Ceptolate	AF
6209T	Tablet 500 mg	300	5	..	*977.28	a	APO-Mycophenolate	TX
						a	CellCept	RO
						a	Ceptolate	AF
						a	Imulate	QA
						a	Mycophenolate Sandoz	SZ
						a	Pharmacor Mycophenolate 500	CR
6364Y	Powder for oral suspension 1 g per 5 mL, 165 mL	2	5	..	*#517.58		CellCept	RO
	MYCOPHENOLATE SODIUM **Caution** Careful monitoring of patients is mandatory. **Authority required** Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.							
6369F	Tablet (enteric coated) 180 mg (mycophenolic acid)	240	5	..	*394.80		Myfortic	NV
6370G	Tablet (enteric coated) 360 mg (mycophenolic acid)	240	5	..	*783.16		Myfortic	NV
	NATALIZUMAB **Caution** Progressive multifocal leukoencephalopathy has been reported with this drug. **Note** Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program. **Authority required** Initial treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. **Authority required** Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy. **Note** Special Pricing Arrangements apply.							
9624M	Solution concentrate for I.V. infusion 300 mg in 15 mL	1	5	..	2084.88		Tysabri	BD

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	SIROLIMUS						
	Caution						
	Careful monitoring of patients is mandatory.						
	Authority required						
	Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.						
6436R	Tablet 1 mg	200	5	..	*1493.08	Rapamune	PF
6437T	Oral solution 1 mg per mL, 60 mL	2	5	..	*979.86	Rapamune	PF
6457W	Tablet 2 mg	200	5	..	*2939.76	Rapamune	PF
9748C	Tablet 0.5 mg	200	5	..	*758.70	Rapamune	PF

Tumor necrosis factor alpha (TNF-alpha) inhibitors

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

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(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:
(a) who has severe active juvenile idiopathic arthritis; AND
(b) whose parent or authorised guardian has signed a patient acknowledgement; AND
(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND
(d) who has demonstrated either:
(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or
(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:
— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with adalimumab by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has a documented history of severe active juvenile idiopathic arthritis; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required

Initial 3 ('grandfather' patients).

Initial PBS-subsidised supply for continuing treatment with adalimumab, by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has a documented history of severe active juvenile idiopathic arthritis; and
(b) was receiving treatment with adalimumab prior to 1 March 2010; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and
(d) is receiving treatment with adalimumab at the time of application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 24 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to this initial course of PBS-subsidised therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A patient may only qualify for PBS-subsidised treatment under this restriction once.

Authority required

Continuing treatment.

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient:
(a) who has a documented history of severe active juvenile idiopathic arthritis; and
(b) who has demonstrated an adequate response to treatment with adalimumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab.

An adequate response to treatment is defined as:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

9678J	Injection 20 mg in 0.4 mL pre-filled syringe	2	..	..	1676.42	Humira	AB
9679K	Injection 40 mg in 0.8 mL pre-filled syringe	2	..	..	1676.42	Humira	AB
9680L	Injection 40 mg in 0.8 mL pre-filled pen	2	..	..	1676.42	Humira	AB

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:
(a) who has severe active juvenile idiopathic arthritis; AND
(b) whose parent or authorised guardian has signed a patient acknowledgement; AND
(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND
(d) who has demonstrated either:
(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or
(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:
— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required
Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with etanercept by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has a documented history of severe active juvenile idiopathic arthritis; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and
(c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with etanercept may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required
Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient:
(a) who has a documented history of severe active juvenile idiopathic arthritis; and
(b) who has demonstrated an adequate response to treatment with etanercept; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

6367D	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	1	..	..	854.02	Enbrel	PF

ETANERCEPT
Note
Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required

Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient 18 years or older:
(a) who has a documented history of severe active juvenile idiopathic arthritis; and
(b) who has demonstrated an adequate response to treatment with etanercept; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of 24 weeks of treatment will be approved under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. Where a patient with severe active juvenile idiopathic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed.						
9615C	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	..	..	1676.43	Enbrel	PF
9641K	Injection 50 mg in 1 mL single use auto-injector, 4	1	..	..	1676.43	Enbrel	PF

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required

Initial 2 (change or re-commencement for all patients)
Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with infliximab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required

Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated an adequate response to treatment with infliximab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au]. All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with infliximab will be authorised under this criterion. At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone. All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with infliximab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.						
6448J	Powder for I.V. infusion 100 mg	1	..	..	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with infliximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with infliximab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** Special Pricing Arrangements apply.						
6397Q	Powder for I.V. infusion 100 mg	1	..	..	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these

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revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Authority required
Initial 2
Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with infliximab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required
Continuing treatment
Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

6496X	Powder for I.V. infusion 100 mg	1	..	..	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial treatment of Crohn disease in a patient assessed by CDAI.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2
Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximb consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Authority required
Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or
(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial 1
Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required
Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 3 (grandfather)
Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Initial 3
Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.						
9613Y	Powder for I.V. infusion 100 mg	1	..	..	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time

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the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;
(ii) an 8 week course of enteral nutrition;
(iii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastoenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of

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infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of moderate to severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:
(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and
(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and (ii) the signed patient acknowledgement. The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab. Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients may qualify for PBS-subsidised treatment under this restriction once only.						
9612X	Powder for I.V. infusion 100 mg	1	..	..	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has an externally draining enterocutaneous or rectovaginal fistula; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

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A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

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It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:
(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) is receiving treatment with infliximab at the time of application; and
(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The fistula assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab. Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
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INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial

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treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of

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the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

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At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

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(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Note No applications for increased repeats will be authorised.						
9617E	Powder for I.V. infusion 100 mg	1	..	..	788.19	Remicade	JC

Interleukin inhibitors

TOCILIZUMAB

Note

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with tocilizumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required
Continuing treatment

Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with tocilizumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats of each strength may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Note Special Pricing Arrangements apply.						
9671B	Concentrate for injection 80 mg in 4 mL	1	..	..	200.78	Actemra	RO
9672C	Concentrate for injection 200 mg in 10 mL	1	..	..	492.31	Actemra	RO
9673D	Concentrate for injection 400 mg in 20 mL	1	..	..	978.20	Actemra	RO

TOCILIZUMAB

Note

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with tocilizumab.

A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required
Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND
(b) has polyarticular course disease and either:
(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate

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response):
— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or
(ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR
(c) has refractory systemic symptoms, demonstrated by:
— an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND
(d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

(1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:
(a) in a patient with polyarticular course disease:
(i) an active joint count of at least 20 active (swollen and tender) joints; OR
(ii) at least 4 active joints from the following list:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
(b) in a patient with refractory systemic symptoms:
(i) an active joint count of at least 2 active joints; AND
(ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR
(iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

(2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.
Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.
If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.
If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
(ii) details of prior treatment including dose and duration of treatment;
(iii) pathology reports detailing CRP and platelet count where appropriate; and
(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

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Authority required
Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; AND
(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND
(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Authority required
Initial 3 ('grandfather' patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; and
(b) was receiving treatment with tocilizumab prior 1 November 2011; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and
(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) pathology reports detailing CRP and platelet count where appropriate; and
(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have

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failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once.

Authority required

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; AND
(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:
(a) in a patient with polyarticular course disease:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
(b) in a patient with refractory systemic symptoms:
(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR
(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR
(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note

Special Pricing Arrangements apply.

1419Q	Concentrate for injection 80 mg in 4 mL	1	..	..	200.78	Actemra	RO
1423X	Concentrate for injection 200 mg in 10 mL	1	..	..	492.31	Actemra	RO

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1464C	Concentrate for injection 400 mg in 20 mL	1	..	..	978.20		Actemra	RO

Calcineurin inhibitors

CYCLOSPORIN
Caution
Careful monitoring of patients is mandatory.

Authority required
For use by organ or tissue transplant recipients.

6109M	Solution concentrate for I.V. infusion 50 mg in 1 mL	10	..	..	64.52		Sandimmun	NV

CYCLOSPORIN
Caution
Careful monitoring of patients is mandatory.

Authority required
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required;

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate;

Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life;

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired;

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate.

6125J	Oral liquid 100 mg per mL, 50 mL	4	5	..	*1309.58		Neoral	NV
6232B	Capsule 10 mg	120	5	..	*84.82		Neoral 10	NV
6352H	Capsule 25 mg	120	5	..	*166.14	[a]	Cicloral	SZ
						[a]	Neoral 25	NV
6353J	Capsule 50 mg	120	5	..	*338.74	[a]	Cicloral	SZ
				[B]4.40	*343.14	[a]	Neoral 50	NV
6354K	Capsule 100 mg	120	5	..	*683.54	[a]	Cicloral	SZ
				[B]5.80	*689.34	[a]	Neoral 100	NV

TACROLIMUS
Caution
Careful monitoring of patients is mandatory.

Authority required
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required.

6216E	Capsule 1 mg	200	5	..	*688.32	[a]	Prograf	JC
						[a]	Tacrolimus Sandoz	SZ
6217F	Capsule 5 mg	100	5	..	*1684.80	[a]	Prograf	JC
						[a]	Tacrolimus Sandoz	SZ
6328C	Capsule 0.5 mg	200	5	..	*347.38	[a]	Prograf	JC
						[a]	Tacrolimus Sandoz	SZ
9681M	Capsule 0.5 mg (once daily prolonged release)	60	5	..	*108.78		Prograf XL	JC
9682N	Capsule 1 mg (once daily prolonged release)	120	5	..	*415.56		Prograf XL	JC
9683P	Capsule 5 mg (once daily prolonged release)	60	5	..	*1029.30		Prograf XL	JC

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Other immunosuppressants

LENALIDOMIDE

Note

Any queries concerning the arrangements to prescribe lenalidomide may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Any queries concerning patients who are enrolled on the Lenalidomide Compassionate program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). These patients must demonstrate they met initial criteria prior to commencing treatment on the compassionate program and also demonstrate they do not have progressive disease. Baseline and current pathology reports must be submitted with the initial application.

Applications for authority to prescribe lenalidomide should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of a patient with a histological diagnosis of multiple myeloma who has progressive disease after at least 1 prior therapy and who has undergone or is ineligible for a primary stem cell transplant. The patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria.

Thalidomide treatment failure is defined as:
(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:
(1) less than a 25% reduction in serum or urine M protein; or
(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

Lenalidomide will only be subsidised for patients with multiple myeloma who are not receiving concomitant PBS-subsidised bortezomib.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response.

To enable confirmation by Medicare Australia, current diagnostic reports of at least one of the following are required:
(a) the level of serum monoclonal protein; or

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(b) Bence-Jones proteinuria — the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (either previous or current serum M protein less than 10 g per L and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must be provided; and
(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment.

Note
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required
Continuing PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of multiple myeloma in a patient who has previously been issued with an authority prescription for lenalidomide and who does not have progressive disease.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note
Special Pricing Arrangements apply.

9642L	Capsule 5 mg	21	..	..	5438.80	Revlimid	CJ
9643M	Capsule 10 mg	21	..	..	5689.75	Revlimid	CJ
9644N	Capsule 15 mg	21	..	..	6628.03	Revlimid	CJ
9645P	Capsule 25 mg	21	..	..	6980.62	Revlimid	CJ

RITUXIMAB

Note
Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe rituximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

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Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and
(c) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(d) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date it was conducted.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and
(c) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with rituximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

A maximum of two infusions will be authorised under this restriction.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be provided to Medicare Australia no later than 4 weeks from the date of assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	clinical immunologist with expertise in the management of rheumatoid arthritis, of adults: (a) who have a documented history of severe active rheumatoid arthritis; and (b) who have demonstrated an adequate response to treatment with rituximab; and (c) whose most recent course of PBS-subsidised bDMARD treatment was with rituximab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or — shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of two infusions will be authorised under this restriction. Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** Special Pricing Arrangements apply.						
9611W	Solution for I.V. infusion 500 mg in 50 mL	1	..	..	2309.99	Mabthera	RO
	THALIDOMIDE **Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment. **Authority required** Multiple myeloma. **Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.						
6469L	Capsule 50 mg	112	..	..	*1726.42	Thalomid	CJ
9684Q	Capsule 100 mg	56	..	..	*1726.42	Thalomid	CJ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	

Musculo-skeletal system

Muscle relaxants

Muscle relaxants, centrally acting agents

Other centrally acting agents

BACLOFEN

Authority required

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin;

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis;

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury;

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease.

6284R	Intrathecal injection 10 mg in 5 mL	10	..	..	*1530.12		Lioresal Intrathecal	NV

Drugs for treatment of bone diseases

Drugs affecting bone structure and mineralization

Bisphosphonates

DISODIUM PAMIDRONATE

Authority required

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 15 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 15 mg are equivalent for the purposes of substitution.

6286W	Concentrated injection 15 mg in 5 mL	4	2	..	*224.74	[a]	Pamisol	HH
6290C	Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL	1	2	..	224.73	[a]	Aredia 15 mg	NV

DISODIUM PAMIDRONATE

Authority required

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

6279L	Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL	1	2	..	224.73	[a]	Aredia 30 mg	NV
6287X	Concentrated injection 30 mg in 10 mL	2	2	..	*224.74	[a]	Pamisol	HH

DISODIUM PAMIDRONATE

Authority required

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

6288Y	Concentrated injection 60 mg in 10 mL	1	2	..	224.72		Pamisol	HH

DISODIUM PAMIDRONATE

Authority required

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	
	Authority required Multiple myeloma; Bone metastases from breast cancer. **Note** Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.							
6223M	Injection set containing 1 vial powder for I.V. infusion 90 mg and 1 ampoule solvent 10 mL	1	11	..	333.86	[a]	Aredia 90 mg	NV
6289B	Concentrated injection 90 mg in 10 mL	1	11	..	333.86	[a]	Pamisol	HH
	IBANDRONIC ACID **Authority required** Bone metastases from breast cancer.							
9619G	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	1	11	..	361.43		Bondronat	HH
	ZOLEDRONIC ACID **Authority required** Multiple myeloma; Bone metastases from breast cancer; Bone metastases from hormone-resistant prostate cancer; Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy. **Note** Special Pricing Arrangements apply.							
6371H	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	1	11	..	474.42		Zometa	NV

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	

Nervous system

Anti-Parkinson drugs

Dopaminergic agents

Dopa and dopa derivatives

LEVODOPA with CARBIDOPA

Authority required

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic.

Note

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

9744W	Intestinal gel 20 mg-5 mg per mL, 100 mL	56	5	..	*11582.42		Duodopa	AB

Dopamine agonists

APOMORPHINE HYDROCHLORIDE

Authority required

Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy.

9607P	Injection 20 mg in 2 mL	5	..	..	88.28		Apomine	HH
9640J	Injection 50 mg in 5 mL	5	..	..	208.86		Apomine	HH
9647R	Solution for subcutaneous infusion 50 mg in 10 mL pre-filled syringe	5	..	..	208.86		Apomine PFS	HH

Psycholeptics

Antipsychotics

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Authority required

Schizophrenia in patients who are non-responsive to other neuroleptic agents;

Schizophrenia in patients who are intolerant of other neuroleptic agents.

6101D	Tablet 25 mg	100	..	..	60.41	[a]	Clopine 25	HH
						[a]	Clozaril 25	NV
6102E	Tablet 100 mg	100	..	..	201.38	[a]	Clopine 100	HH
						[a]	Clozaril 100	NV
6417R	Tablet 50 mg	100	..	..	110.41		Clopine 50	HH
6418T	Tablet 200 mg	100	..	..	396.36		Clopine 200	HH
9632Y	Oral liquid 50 mg per mL, 100 mL	1	..	..	146.82		Clopine Suspension	HH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Respiratory system

Drugs for obstructive airway diseases

Other systemic drugs for obstructive airway diseases

Other systemic drugs for obstructive airway diseases

OMALIZUMAB

Note

Any queries concerning the arrangements to prescribe omalizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe omalizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(2) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.

(5) Monitoring of patients.

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:
(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or
(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or
(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

(e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

(f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:
(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND
(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

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If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:
(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and
(iii) the signed patient acknowledgement; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.medicareaustralia.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:
(a) has a documented history of severe allergic asthma; and
(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

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The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

Authority required

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:
(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or
(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or
(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) past or current evidence of atopy, documented by skin prick testing or RAST; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and

(e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:
(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, and
(ii) may have included maintenance dose oral corticosteroids; and

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	(f) has demonstrated an adequate response to treatment with omalizumab. A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; (ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ); (iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or (iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab. Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and (iii) the signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks. An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment. Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment. Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. **Note** Special Pricing Arrangements apply.						
9746Y	Powder for injection 150 mg with diluent	1	..	..	448.42	Xolair	NV

Cough and cold preparations

Expectorants, excl. combinations with cough suppressants

Mucolytics

DORNASE ALFA

Authority required

Use by cystic fibrosis patients who satisfy all of the following criteria:
(1) are 5 years of age or older;

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(2) have a FVC greater than 40% predicted for age, gender and height;
(3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);
(4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial.

In order for patients to be eligible for participation in the HSD program, the following conditions must be met:
(1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;
(2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;
(3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;
(4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily;
(5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily;
(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;
(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;
(8) Other aspects of treatment, such as physiotherapy, must be continued;
(9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period).

Note
It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.

Authority required
Treatment of cystic fibrosis in a patient less than 5 years of age who has:
(1) A severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring frequent hospital admissions more frequently than 3 times per year; or
(2) Significant bronchiectasis on chest high resolution computed tomography scan; or
(3) Severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or
(4) Severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

In order for the patient to be eligible for participation in the HSD program, the following conditions must be met:
(1) The patient must be assessed at a cystic fibrosis clinic/centre which is under the supervision of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis, and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;
(2) Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. Further reassessments are to be undertaken and documented yearly.

Note
It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.

Authority required
Grandfather — continuing for patients five years or older
Continuation of treatment of cystic fibrosis in a patient 5 years of age or older, who initiated treatment with dornase alfa at an age of less than 5 years and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note
It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.

Authority required
Grandfather — for patients less than five years of age who initiated dornase alfa prior to listing
Treatment of cystic fibrosis in a patient less than 5 years of age who initiated treatment with dornase alfa prior to 1 November 2009 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be

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	undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.						
	Note It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.						
6120D	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	60	5	..	*2406.42	Pulmozyme	RO

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Sensory organs

Ophthalmologicals

Antiinfectives

Antivirals

GANCICLOVIR

Authority required

Cytomegalovirus retinitis in severely immunocompromised patients.

6256G	Intravitreal implant 4.5 mg	1	..	..	6046.42	Vitrasert	BU

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Various

All other therapeutic products

All other therapeutic products

Iron chelating agents

DEFERASIROX

Authority required

Chronic iron overload in patients with disorders of erythropoiesis.

Note

Special Pricing Arrangements apply.

6499C	Tablet 125 mg (dispersible)	168	5	..	*1447.92	Exjade	NV
6500D	Tablet 250 mg (dispersible)	168	5	..	*2849.34	Exjade	NV
9600G	Tablet 500 mg (dispersible)	168	5	..	*5652.24	Exjade	NV

DEFERIPRONE

Authority required

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy;

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective.

6416Q	Tablet 500 mg	600	5	..	*2749.80	Ferriprox	OA
9638G	Oral solution 100 mg per mL, 250 mL	5	5	..	*1172.82	Ferriprox	OA

DESFERRIOXAMINE MESYLATE

Authority required

Disorders of erythropoiesis associated with treatment-related chronic iron overload.

6113R	Powder for injection 500 mg	400	5	..	*3772.02 [a]	Hospira Pty Limited	HH
				[B]308.80	*4080.82 [a]	Desferal 500 mg	NV
6270B	Powder for injection 2 g	60	5	..	*2281.62 [a]	Hospira Pty Limited	HH
				[B]22.80	*2304.42 [a]	Desferal 2 g	NV

Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority required

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.
Management includes initiation, stabilisation and review of therapy as required;

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.
Management includes initiation, stabilisation and review of therapy as required.

Note

Not to be used in combination with sevelamer.

9635D	Tablet, chewable, 500 mg (as carbonate hydrate)	180	5	..	*550.90	Fosrenol	ZI
9636E	Tablet, chewable, 750 mg (as carbonate hydrate)	180	5	..	*828.60	Fosrenol	ZI
9637F	Tablet, chewable, 1000 mg (as carbonate hydrate)	180	5	..	*932.04	Fosrenol	ZI

SEVELAMER HYDROCHLORIDE

Authority required

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.
Management includes initiation, stabilisation and review of therapy as required;

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.
Management includes initiation, stabilisation and review of therapy as required.

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	Note Not to be used in combination with lanthanum.						
9620H	Tablet 800 mg	360	5	..	*651.22	Renagel	GZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Blood and blood forming organs

Antihemorrhagics

Vitamin K and other hemostatics

Other systemic hemostatics

ELTROMBOPAG

Note

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:
(1) Splenectomised and:
(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
OR
(2) Not splenectomised and:
(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L;
OR
(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

Authority required

Initial (grandfather patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in

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whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Note
No applications for increased repeats will be authorised.

Authority required
Continuing therapy or re-initiation after a break in therapy
First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Note
No applications for increased repeats will be authorised.

Authority required
Second and subsequent applications for continuing therapy
Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
No applications for increased repeats will be authorised.

5825N	Tablet 25 mg (as olamine)	28	5	..	1512.00	Revolade	GK
5826P	Tablet 50 mg (as olamine)	28	5	..	3024.00	Revolade	GK

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ROMIPLOSTIM

Note

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:
(1) Splenectomised and:
(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
OR
(2) Not splenectomised and:
(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L;
OR
(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Authority required

Initial (grandfather patients)
Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in

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whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required
Continuing therapy or re-initiation after a break in therapy
First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required
Second and subsequent applications for continuing therapy
Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

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	AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses of higher than 10 micrograms/kg/week. **Note** Special Pricing Arrangements apply.						
9696H	Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted)	1	..	..	977.50	Nplate	AN
9698K	Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted)	1	..	..	1955.00	Nplate	AN

Antianemic preparations

Other antianemic preparations

Other antianemic preparations

DARBEPOETIN ALFA
Authority required (STREAMLINED)
3334
Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

5637Q	Injection 10 micrograms in 0.4 mL pre-filled syringe	8	5	..	*356.08	Aranesp	AN
5638R	Injection 20 micrograms in 0.5 mL pre-filled syringe	8	5	..	*670.62	Aranesp	AN
5639T	Injection 30 micrograms in 0.3 mL pre-filled syringe	8	5	..	*917.46	Aranesp	AN
5640W	Injection 40 micrograms in 0.4 mL pre-filled syringe	8	5	..	*1113.60	Aranesp	AN
5641X	Injection 50 micrograms in 0.5 mL pre-filled syringe	8	5	..	*1376.78	Aranesp	AN
5642Y	Injection 60 micrograms in 0.3 mL pre-filled syringe	8	5	..	*1616.66	Aranesp	AN
5643B	Injection 150 micrograms in 0.3 mL pre-filled syringe	8	5	..	*3904.50	Aranesp	AN
5644C	Injection 80 micrograms in 0.4 mL pre-filled syringe	8	5	..	*2128.00	Aranesp	AN
5645D	Injection 20 micrograms in 0.5 mL pre-filled injection pen	8	5	..	*670.64	Aranesp SureClick	AN
5646E	Injection 40 micrograms in 0.4 mL pre-filled injection pen	8	5	..	*1113.60	Aranesp SureClick	AN
5647F	Injection 60 micrograms in 0.3 mL pre-filled injection pen	8	5	..	*1616.64	Aranesp SureClick	AN
5648G	Injection 80 micrograms in 0.4 mL pre-filled injection pen	8	5	..	*2128.00	Aranesp SureClick	AN
5649H	Injection 100 micrograms in 0.5 mL pre-filled injection pen	8	5	..	*2620.48	Aranesp SureClick	AN
5650J	Injection 150 micrograms in 0.3 mL pre-filled injection pen	8	5	..	*3904.48	Aranesp SureClick	AN
5651K	Injection 100 micrograms in 0.5 mL pre-filled syringe	8	5	..	*2620.50	Aranesp	AN

EPOETIN ALFA
Authority required (STREAMLINED)
3334
Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

5713Q	Injection 20,000 units in 0.5 mL pre-filled syringe	12	5	..	*3876.00	Eprex 20,000	JC
5714R	Injection 1,000 units in 0.5 mL pre-filled syringe	12	5	..	*279.30	Eprex 1000	JC
5715T	Injection 5,000 units in 0.5 mL pre-filled syringe	12	5	..	*1057.34	Eprex 5000	JC
5716W	Injection 6,000 units in 0.6 mL pre-filled syringe	12	5	..	*1255.14	Eprex 6000	JC
5717X	Injection 8,000 units in 0.8 mL pre-filled syringe	12	5	..	*1627.92	Eprex 8000	JC

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5718Y	Injection 40,000 units in 1 mL pre-filled syringe	2	5	..	*1254.00	Eprex 40,000	JC
5719B	Injection 2,000 units in 0.5 mL pre-filled syringe	12	5	..	*516.80	Eprex 2000	JC
5720C	Injection 3,000 units in 0.3 mL pre-filled syringe	12	5	..	*666.90	Eprex 3000	JC
5721D	Injection 4,000 units in 0.4 mL pre-filled syringe	12	5	..	*849.30	Eprex 4000	JC
5722E	Injection 10,000 units in 1 mL pre-filled syringe	12	5	..	*1970.30	Eprex 10000	JC

EPOETIN BETA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

5724G	Injection 2,000 units in 0.3 mL pre-filled syringe	12	5	..	*516.80	NeoRecormon	RO
5725H	Injection 3,000 units in 0.3 mL pre-filled syringe	12	5	..	*666.90	NeoRecormon	RO
5726J	Injection 4,000 units in 0.3 mL pre-filled syringe	12	5	..	*849.30	NeoRecormon	RO
5727K	Injection 5,000 units in 0.3 mL pre-filled syringe	12	5	..	*1057.36	NeoRecormon	RO
5728L	Injection 6,000 units in 0.3 mL pre-filled syringe	12	5	..	*1255.14	NeoRecormon	RO
5729M	Injection 10,000 units in 0.6 mL pre-filled syringe	12	5	..	*1970.30	NeoRecormon	RO
5730N	Injection 20,000 units in 0.6 mL pre-filled syringe	12	5	..	*3876.00	NeoRecormon	RO

EPOETIN LAMBDA

Note

Epoetin lambda should only be administered by the intravenous route.

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

9587N	Injection 4,000 units in 0.4 mL pre-filled syringe	12	5	..	*804.60	Novicrit	NV
9589Q	Injection 5,000 units in 0.5 mL pre-filled syringe	12	5	..	*1001.70	Novicrit	NV
9591T	Injection 6,000 units in 0.6 mL pre-filled syringe	12	5	..	*1189.08	Novicrit	NV
9594Y	Injection 8,000 units in 0.8 mL pre-filled syringe	12	5	..	*1542.24	Novicrit	NV
9596C	Injection 10,000 units in 1 mL pre-filled syringe	12	5	..	*1866.60	Novicrit	NV
9668W	Injection 1,000 units in 0.5 mL pre-filled syringe	12	5	..	*264.60	Novicrit	NV
9669X	Injection 2,000 units in 1 mL pre-filled syringe	12	5	..	*489.60	Novicrit	NV
9670Y	Injection 3,000 units in 0.3 mL pre-filled syringe	12	5	..	*631.80	Novicrit	NV

METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

5794Y	Injection 30 micrograms in 0.3 mL pre-filled syringe	2	5	..	*369.18	Mircera	RO
5795B	Injection 50 micrograms in 0.3 mL pre-filled syringe	2	5	..	*615.30	Mircera	RO
5796C	Injection 75 micrograms in 0.3 mL pre-filled syringe	2	5	..	*896.02	Mircera	RO
5797D	Injection 100 micrograms in 0.3 mL pre-filled syringe	2	5	..	*1158.82	Mircera	RO
5798E	Injection 120 micrograms in 0.3 mL pre-filled syringe	2	5	..	*1341.64	Mircera	RO
5799F	Injection 200 micrograms in 0.3 mL pre-filled syringe	2	5	..	*1924.30	Mircera	RO
5800G	Injection 360 micrograms in 0.6 mL pre-filled syringe	2	5	..	*3326.52	Mircera	RO

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Cardiovascular system

Antihypertensives

Other antihypertensives

Other antihypertensives

AMBRISENTAN

Caution

Ambrisentan is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

Note

Any queries concerning the arrangements to prescribe ambrisentan may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

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Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(c) WHO Functional Class IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (change or re-commencement for all patients)
Application for initial treatment with ambrisentan of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised ambrisentan after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with ambrisentan; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than ambrisentan.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].						
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Authority required						
	Continuing treatment (all patients) Continuing PBS-subsidised treatment with ambrisentan of patients who have received approval for initial PBS-subsidised treatment with ambrisentan and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of ambrisentan treatment [see Note for definition of response].						
	Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6MWT.						
	The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.						
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Note						
	Special Pricing Arrangements apply.						
5607D	Tablet 5 mg	30	..	..	4035.00	Volibris	GK
5608E	Tablet 10 mg	30	..	..	4035.00	Volibris	GK
	BOSENTAN MONOHYDRATE						
	Caution						
	Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.						
	Note						
	Any queries concerning the arrangements to prescribe bosentan monohydrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written applications for authority to prescribe PAH agents should be forwarded to:						
	Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001;						
	Note						
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.						
	Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.						
	PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.						
	The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with: (a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.
All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(c) WHO Functional Class IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(e) WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Applications for authorisation must be in writing and must include:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients)
Application for initial treatment with bosentan monohydrate of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than bosentan monohydrate.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Cessation of treatment (all patients)
Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to connective tissue disease or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.

Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements].

Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month.

Note

Special Pricing Arrangements apply.

5618Q	Tablet 62.5 mg (base)	60	..	..	4035.00	Tracleer	AT
5619R	Tablet 125 mg (base)	60	..	..	4035.00	Tracleer	AT

EPOPROSTENOL SODIUM

Note

Any queries concerning the arrangements to prescribe epoprostenol sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class IV primary pulmonary hypertension; OR
(b) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
(5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
5030R	Powder for I.V. infusion 500 micrograms (base) infusion administration set	1	..	..	39.62	Flolan Kit	GK
5035B	Powder for I.V. infusion 1.5 mg (base) infusion administration set	1	..	..	79.23	Flolan Kit	GK

ILOPROST TROMETAMOL

Note

Any queries concerning the arrangements to prescribe iloprost trometamol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with iloprost and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

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Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class IV primary pulmonary hypertension; OR
(c) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
(d) WHO Functional Class IV drug-induced pulmonary arterial hypertension.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR
(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than iloprost trometamol; OR
(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
(5) for WHO Functional Class III patients, where this is the first application for iloprost trometamol, assessment details of the PBS-subsidised PAH

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agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Special Pricing Arrangements apply.

5751Q	Solution for inhalation 20 micrograms (base) in 2 mL	30	..	..	1076.00	Ventavis	BN

SILDENAFIL CITRATE

Note

Any queries concerning the arrangements to prescribe sildenafil citrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO

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Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

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The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.
All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients with one of the following:
(a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; OR
(b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than sildenafil citrate.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sildenafil citrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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TADALAFIL

Note

Any queries concerning the arrangements to prescribe tadalafil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter

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(RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.
All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

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The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO;

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients)

Application for initial treatment with tadalafil of patients with one of the following:

(a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised tadalafil after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with tadalafil; OR

(b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than tadalafil.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with tadalafil of patients who have received approval for initial PBS-subsidised treatment with tadalafil, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of tadalafil treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
1308W	Tablet 20 mg	56	..	..	838.53	Adcirca	LY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Systemic hormonal preparations, excl. sex hormones and insulins

Pituitary and hypothalamic hormones and analogues

Hypothalamic hormones

Somatostatin and anaolgues

LANREOTIDE ACETATE

Authority required (STREAMLINED)

3387

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment.

5776B	Powder for suspension for injection 30 mg (base) with diluent ampoule	2	11	..	*1500.00	Somatuline LA	IS

LANREOTIDE ACETATE

Authority required (STREAMLINED)

3388

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment;

3389

Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

5777C	Injection 60 mg (base) in single dose pre-filled syringe	2	11	..	*2690.00	Somatuline Autogel	IS
5778D	Injection 90 mg (base) in single dose pre-filled syringe	2	11	..	*3580.00	Somatuline Autogel	IS
5779E	Injection 120 mg (base) in single dose pre-filled syringe	2	11	..	*4480.00	Somatuline Autogel	IS

OCTREOTIDE

Authority required (STREAMLINED)

3407

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily;

3408

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	
	Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.							
9508K	Injection 50 micrograms (as acetate) in 1 mL	90	11	..	*619.02	[a]	Hospira Pty Limited	HH
						[a]	Octreotide MaxRx	XF
						[a]	Sandostatin 0.05	NV
9509L	Injection 100 micrograms (as acetate) in 1 mL	90	11	..	*1236.42	[a]	Hospira Pty Limited	HH
						[a]	Octreotide MaxRx	XF
						[a]	Sandostatin 0.1	NV
9510M	Injection 500 micrograms (as acetate) in 1 mL	90	11	..	*6194.52	[a]	Hospira Pty Limited	HH
						[a]	Octreotide MaxRx	XF
						[a]	Sandostatin 0.5	NV

OCTREOTIDE

Authority required (STREAMLINED)

3409

Acromegaly in a patient controlled on Sandostatin subcutaneous injections.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months of treatment;

3410

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections.
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

9511N	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	1	11	..	1306.86	Sandostatin LAR	NV
9512P	Injection (modified release) 20 mg (as acetate), vial and diluent syringe	1	11	..	1739.81	Sandostatin LAR	NV
9513Q	Injection (modified release) 30 mg (as acetate), vial and diluent syringe	1	11	..	2177.46	Sandostatin LAR	NV

Calcium homeostasis

Anti-parathyroid agents

Other anti-parathyroid agents

CINACALCET

Authority required (STREAMLINED)

3323

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy.

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Authority required (STREAMLINED)

3324

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Note During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability. During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months. **Note** Special Pricing Arrangements apply.						
5621W	Tablet 30 mg (as hydrochloride)	56	5	..	*593.72	Sensipar	AN
5622X	Tablet 60 mg (as hydrochloride)	56	5	..	*1187.44	Sensipar	AN
5623Y	Tablet 90 mg (as hydrochloride)	56	5	..	*1781.16	Sensipar	AN

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Antiinfectives for systemic use

Antibacterials for systemic use

Macrolides, lincosamides and streptogramins

Macrolides

AZITHROMYCIN
Authority required (STREAMLINED)
3317
Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

5616N	Tablet 600 mg (as dihydrate)	16	5	..	*113.96	Zithromax	PF

CLARITHROMYCIN
Authority required (STREAMLINED)
3325
Treatment of Mycobacterium avium complex infections.

5624B	Tablet 500 mg	100	2	..	55.32	Klacid	AB
5625C	Tablet 250 mg	100	2	..	27.71	Klacid	AB

Antimycobacterials

Drugs for treatment of tuberculosis

Antibiotics

RIFABUTIN
Authority required (STREAMLINED)
3415
Treatment of Mycobacterium avium complex infections in HIV-positive patients;

3317
Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

9541E	Capsule 150 mg	120	5	..	*588.00	Mycobutin	PF

Antivirals for systemic use

Direct acting antivirals

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

CIDOFOVIR
Authority required (STREAMLINED)
3322
Treatment of cytomegalovirus retinitis in patients with AIDS.

5620T	Solution for I.V. infusion 375 mg (anhydrous) in 5 mL single use vial	4	3	..	*3600.00	Vistide	GI

GANCICLOVIR
Authority required (STREAMLINED)
3379
Cytomegalovirus retinitis in severely immunocompromised patients;

3380
Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease;

3381
Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease.

5749N	Powder for I.V. infusion 500 mg (as sodium)	10	1	..	*560.00	Cymevene	RO

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	
	VALACICLOVIR							
	Authority required (STREAMLINED)							
	3419							
	Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.							
9568N	Tablet 500 mg (as hydrochloride)	500	2	..	*2115.90	[a]	APO-Valaciclovir	TX
						[a]	Valaciclovir RBX	RA
						[a]	Valtrex	GK
						[a]	Valvala	NV
						[a]	Zelitrex	GM
	VALGANCICLOVIR HYDROCHLORIDE							
	Authority required (STREAMLINED)							
	3420							
	Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome;							
	3421							
	Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease.							
9569P	Tablet 450 mg (base)	120	5	..	*4491.60		Valcyte	RO
9655E	Powder for oral solution 50 mg (base) per mL, 100 mL	11	5	..	*4574.79		Valcyte	RO

Phosphonic acid derivatives

	FOSCARNET SODIUM							
	Authority required (STREAMLINED)							
	3322							
	Treatment of cytomegalovirus retinitis in patients with AIDS;							
	3378							
	Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection.							
5747L	I.V. infusion 24 mg per mL, 250 mL	6	1	..	1177.50		Foscavir	IX

Protease inhibitors

	ATAZANAVIR							
	Authority required (STREAMLINED)							
	3588							
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;							
	3589							
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.							
5612J	Capsule 300 mg (as sulfate)	60	5	..	*1043.82		Reyataz	BQ
5613K	Capsule 150 mg (as sulfate)	120	5	..	*1043.82		Reyataz	BQ
5614L	Capsule 200 mg (as sulfate)	120	5	..	*1391.76		Reyataz	BQ
5615M	Capsule 100 mg (as sulfate)	120	5	..	*695.88		Reyataz	BQ
	DARUNAVIR							
	Authority required (STREAMLINED)							
	3941							
	Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance, and who has not demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.							
5821J	Tablet 400 mg (as ethanolate)	120	5	..	*1398.28		Prezista	JC

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	DARUNAVIR						
	Authority required (STREAMLINED)						
	3595						
	Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
3392M	Tablet 600 mg (as ethanolate)	120	5	..	*2097.42	Prezista	JC
5653M	Tablet 150 mg (as ethanolate)	240	5	..	1048.71	Prezista	JC
	FOSAMPRENAVIR						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5745J	Oral liquid 50 mg (as calcium) per mL, 225 mL	8	5	..	*812.48	Telzir	VI
5746K	Tablet 700 mg (as calcium)	120	5	..	*758.32	Telzir	VI
	INDINAVIR						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5752R	Capsule 400 mg (as sulfate)	360	5	..	*910.00	Crixivan 400 mg	MK
	RITONAVIR						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
9542F	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	10	5	..	*910.00	Norvir	AB
9660K	Tablet 100 mg	720	5	..	*982.80	Norvir	AB
	SAQUINAVIR						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
9545J	Tablet 500 mg (as mesylate)	240	5	..	*1011.12	Invirase	RO

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	TIPRANAVIR **Authority required (STREAMLINED)** ***3601*** Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. **Note** Special Pricing Arrangements apply.						
9567M	Capsule 250 mg	240	5	..	*2142.00	Aptivus	BY
	TIPRANAVIR **Authority required (STREAMLINED)** ***3603*** Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with ritonavir in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. **Note** Special Pricing Arrangements apply.						
9656F	Oral liquid 100 mg per mL, 95 mL	7	5	..	*2374.05	Aptivus	BY

Nucleoside and nucleotide reverse transcriptase inhibitors

	ABACAVIR **Authority required (STREAMLINED)** ***3588*** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; ***3589*** Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5601T	Tablet 300 mg (as sulfate)	120	5	..	*564.00	Ziagen	VI
5602W	Oral solution 20 mg (as sulfate) per mL, 240 mL	8	5	..	*657.12	Ziagen	VI
	ADEFOVIR DIPIVOXIL **Authority required (STREAMLINED)** ***3973*** Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance; ***3974*** Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. **Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
5606C	Tablet 10 mg	60	5	..	*1250.00	Hepsera	GI

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	DIDANOSINE **Authority required (STREAMLINED)** ***3588*** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; ***3589*** Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5663C	Capsule 125 mg (containing enteric coated beadlets)	60	5	..	*280.86	Videx EC	BQ
5664D	Capsule 200 mg (containing enteric coated beadlets)	60	5	..	*326.80	Videx EC	BQ
5665E	Capsule 250 mg (containing enteric coated beadlets)	60	5	..	*408.48	Videx EC	BQ
5666F	Capsule 400 mg (containing enteric coated beadlets)	60	5	..	*653.58	Videx EC	BQ
	EMTRICITABINE **Authority required (STREAMLINED)** ***3588*** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; ***3589*** Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5709L	Capsule 200 mg	60	5	..	*564.00	Emtriva	GI
	ENTECAVIR MONOHYDRATE **Authority required (STREAMLINED)** ***3961*** Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; ***3962*** Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. **Note** PBS-subsidised entecavir monohydrate must be used as monotherapy.						
5711N	Tablet 0.5 mg	60	5	..	*768.60	Baraclude	BQ
	ENTECAVIR MONOHYDRATE **Authority required (STREAMLINED)** ***3964*** Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance; ***3966*** Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. **Note** PBS-subsidised entecavir monohydrate must be used as monotherapy.						
5712P	Tablet 1 mg	60	5	..	*1250.00	Baraclude	BQ

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	LAMIVUDINE **Authority required (STREAMLINED)** ***3961*** Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; ***3962*** Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
5770Q	Tablet 100 mg	56	5	..	*298.72	Zeffix	GK
5771R	Oral solution 5 mg per mL, 240 mL	5	5	..	*349.55	Zeffix	GK
	LAMIVUDINE **Authority required (STREAMLINED)** ***3588*** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; ***3589*** Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5772T	Tablet 150 mg	120	5	..	*564.00	3TC	VI
5773W	Oral solution 10 mg per mL, 240 mL	8	5	..	*691.84	3TC	VI
5774X	Tablet 300 mg	60	5	..	*564.00	3TC	VI
	STAVUDINE **Authority required (STREAMLINED)** ***3588*** Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease; ***3589*** Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
9553T	Capsule 20 mg	120	5	..	*560.00	Zerit	BQ
9554W	Capsule 30 mg	120	5	..	*667.36	Zerit	BQ
9556Y	Capsule 40 mg	120	5	..	*889.80	Zerit	BQ
	TELBIVUDINE **Authority required (STREAMLINED)** ***3969*** Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; ***3970*** Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
9562G	Tablet 600 mg	56	5	..	*501.76	Sebivo	NV

TENOFOVIR

Authority required (STREAMLINED)

3588

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

3589

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

Authority required (STREAMLINED)

3969

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;
(2) Evidence of chronic liver injury as determined by:
(a) Confirmed elevated serum ALT; or
(b) Liver biopsy;

3970

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

3973

Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:
(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or
(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;

3974

Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

9563H	Tablet containing tenofovir disoproxil fumarate 300 mg	60	5	..	*966.20	Viread	GI

ZIDOVUDINE

Authority required (STREAMLINED)

3588

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

3589

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

9570Q	Syrup 10 mg per mL, 200 mL	15	5	..	*673.20	Retrovir	GK
9651Y	Capsule 100 mg	400	5	..	*821.84	Retrovir	GK
9652B	Capsule 250 mg	240	5	..	*1232.76	Retrovir	GK

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Non-nucleoside reverse transcriptase inhibitors

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	EFAVIRENZ						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5706H	Tablet 600 mg	60	5	..	*543.16	Stocrin	MK
5707J	Oral solution 30 mg per mL, 180 mL	7	5	..	*570.29	Stocrin	MK
5708K	Tablet 200 mg	180	5	..	*543.16	Stocrin	MK
	ETRAVIRINE						
	Authority required (STREAMLINED)						
	3597						
	Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
5084N	Tablet 200 mg	120	5	..	*1233.00	Intelence	JC
	NEVIRAPINE						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
9506H	Tablet 200 mg	120	5	..	*543.16	Viramune	BY
9507J	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	10	5	..	*1350.00	Viramune	BY
	NEVIRAPINE						
	Authority required (STREAMLINED)						
	3995						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient who has been stabilised on nevirapine immediate release with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
1132N	Tablet 400 mg (extended release)	60	5	..	*543.16	Viramune XR	BY
	RILPIVIRINE						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
1173R	Tablet 25 mg (as hydrochloride)	60	5	..	*543.16	Edurant	JC

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Antivirals for treatment of HIV infections, combinations						
	ABACAVIR with LAMIVUDINE						
	Authority required (STREAMLINED)						
	3592						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3593						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection.						
5603X	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	60	5	..	*1128.00	Kivexa	VI
	ABACAVIR with LAMIVUDINE and ZIDOVUDINE						
	Authority required (STREAMLINED)						
	3981						
	Initial treatment of HIV infection in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3982						
	Continuing treatment of HIV infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection.						
5604Y	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	120	5	..	*1704.00	Trizivir	VI
	LAMIVUDINE with ZIDOVUDINE						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5775Y	Tablet 150 mg-300 mg	120	5	..	*1157.20	Combivir	VI
	LOPINAVIR with RITONAVIR						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
5789Q	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	10	5	..	*1290.00	Kaletra	AB
5790R	Tablet 100 mg-25 mg	120	5	..	*342.50	Kaletra	AB
5791T	Tablet 200 mg-50 mg	240	5	..	*1370.00	Kaletra	AB
	TENOFOVIR with EMTRICITABINE						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
9564J	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	60	5	..	*1530.20	Truvada	GI

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	TENOFOVIR with EMTRICITABINE and EFAVIRENZ						
	Authority required (STREAMLINED)						
	3985						
	Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3986						
	Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection.						
9565K	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	60	5	..	*2073.36	Atripla	GI
	TENOFOVIR with EMTRICITABINE and RILPIVIRINE						
	Authority required (STREAMLINED)						
	3985						
	Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3986						
	Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection.						
1491L	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride)	60	5	..	*2073.36	Eviplera	GI

Other antivirals

	ENFUVIRTIDE						
	Authority required (STREAMLINED)						
	3597						
	Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
5710M	Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)	2	5	..	*4426.00	Fuzeon	RO
	MARAVIROC						
	Authority required (STREAMLINED)						
	3599						
	Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
5792W	Tablet 150 mg	120	5	..	*1835.40	Celsentri	VI
5793X	Tablet 300 mg	120	5	..	*1835.40	Celsentri	VI
	RALTEGRAVIR						
	Authority required (STREAMLINED)						
	3588						
	Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3589						
	Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
9523F	Tablet 400 mg (as potassium)	120	5	..	*1331.10	Isentress	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Antineoplastic and immunomodulating agents

Antineoplastic agents

Antimetabolites

Pyrimidine analogues

AZACITIDINE

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial PBS-subsidised treatment of a patient with:
(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:
1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
(d) a copy of the full blood examination report; and
(e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
(f) a signed patient acknowledgment form.

No more than three cycles will be authorised.

Note

Special Pricing Arrangements apply.

9597D	Powder for injection 100 mg	14	2	..	*7700.00	Vidaza	CJ

AZACITIDINE

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe azacitidine should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001. **Authority required** Continuing treatment of a patient with: (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR (3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised. **Note** Special Pricing Arrangements apply.						
9598E	Powder for injection 100 mg	14	5	..	*7700.00	Vidaza	CJ

Cytotoxic antibiotics and related substances
Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL
Authority required (STREAMLINED)
3348
Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement;

3349
Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement.

5705G	Suspension for I.V. infusion 20 mg in 10 mL	4	5	..	*2491.96	Caelyx	JC
						Lipodox	ZF

Immunostimulants

Immunostimulants
Colony stimulating factors

FILGRASTIM
Authority required (STREAMLINED)
3357
For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

3358
Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;

3359
Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;

3360
A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;

3361
A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;

3362
A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3363 A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3364 A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3365 A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3366 A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);						
	3367 A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));						
	3368 A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));						
	3369 A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.						
	Authority required (STREAMLINED) ***3370*** A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;						
	3371 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);						
	3372 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;						
	3373 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;						
	3374 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;						
	3375 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);						
	3376 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;						
	3377 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma;						
	3834 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP).						
1123D	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2515.54	TevaGrastim	AS
1126G	Injection 480 micrograms in 0.8 mL single use pre-filled syringe	20	11	..	*4032.58	TevaGrastim	AS

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
5741E	Injection 300 micrograms in 1 mL	20	11	..	*2515.54	Neupogen	AN
5742F	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2515.54	Neupogen	AN
5743G	Injection 480 micrograms in 1.6 mL	20	11	..	*4032.58	Neupogen	AN
5744H	Injection 480 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*4032.58	Neupogen	AN
5829T	Injection 120 micrograms in 0.2 mL single use pre-filled syringe	20	11	..	*1006.22	Nivestim	HH
9692D	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2515.54	Nivestim	HH
9694F	Injection 480 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*4032.58	Nivestim	HH

LENOGRASTIM

Authority required (STREAMLINED)

3392

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy;

3393

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors;

3394

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation;

3395

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

3396

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

3397

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;

3398

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma;

3399

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;

3400

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;

3401

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;

3402

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade);

3403

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma;

3404

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease;

3405

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

5787N	Powder for injection 13,400,000 i.u. (105 micrograms)	20	11	..	*1025.00	Granocyte 13	HH
5788P	Powder for injection 33,600,000 i.u. (263 micrograms)	20	11	..	*2567.20	Granocyte 34	HH

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	PEGFILGRASTIM						
	Authority required (STREAMLINED)						
	3357						
	For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;						
	3362						
	A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3363						
	A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3364						
	A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3365						
	A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3369						
	A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.						
	Authority required (STREAMLINED)						
	3370						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;						
	3371						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);						
	3372						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;						
	3373						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;						
	3374						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;						
	3375						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);						
	3376						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;						
	3377						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma;						
	3834						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP).						
9514R	Injection 6 mg in 0.6 mL single use pre-filled syringe	1	11	..	1925.00	Neulasta	AN

Interferons

INTERFERON ALFA-2a

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Authority required (STREAMLINED) ***3382*** Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase; ***3961*** Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; ***3962*** Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
5759D	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*894.00	Roferon-A	RO
5760E	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1341.00	Roferon-A	RO
5761F	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1787.40	Roferon-A	RO
5762G	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*2681.40	Roferon-A	RO
	INTERFERON ALFA-2b **Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. **Authority required (STREAMLINED)** ***3384*** Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement; ***3382*** Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase; ***3961*** Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; ***3962*** Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
5763H	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*357.48	Intron A Redipen	MK
5764J	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*595.80	Intron A Redipen	MK
5765K	Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*1191.60	Intron A Redipen	MK
5766L	Solution for injection 18,000,000 i.u. in 3 mL single dose vial	15	5	..	*2681.10	Intron A	MK
5767M	Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial	15	5	..	*3723.75	Intron A	MK
5768N	Solution for injection 10,000,000 i.u. in 1 mL single dose vial	15	5	..	*1489.50	Intron A	MK
	INTERFERON GAMMA-1b **Authority required (STREAMLINED)** ***3385*** Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents.						
5769P	Injection 2,000,000 i.u. in 0.5 mL	12	11	..	*2721.80	Imukin	BY

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	PEGINTERFERON ALFA-2a						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	Authority required (STREAMLINED)						
	3977						
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B;						
	3978						
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;						
	3412						
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
9515T	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2331.80	Pegasys	RO
9516W	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2700.46	Pegasys	RO
	RIBAVIRIN and PEGINTERFERON ALFA-2a						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	Caution						
	Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.						
	Authority required (STREAMLINED)						
	3413						
	Patients naive to interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12).						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24 hour access by patients to medical advice; and
(c) an established liver clinic; and
(d) facilities for safe liver biopsy.

Authority required (STREAMLINED)

3414

Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated)

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria:
(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.
The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24 hour access by patients to medical advice; and
(c) an established liver clinic; and
(d) facilities for safe liver biopsy.

9524G	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	2	5	..	*3072.84	Pegasys RBV	RO
9525H	Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	2	5	..	*3085.28	Pegasys RBV	RO
9526J	Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	2	5	..	*3245.82	Pegasys RBV	RO
9527K	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	2	5	..	*3406.36	Pegasys RBV	RO

RIBAVIRIN and PEGINTERFERON ALFA-2b

Caution

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Caution

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Authority required (STREAMLINED)

3949

Patients naive to interferon based therapies (non-pegylated or pegylated)

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients weighing at least 27 kg who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:
(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.
For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.
Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy. **Authority required (STREAMLINED)** ***3414*** Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12. **Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
9529M	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	2	5	..	*2119.74	Pegatron	MK
9530N	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	2	5	..	*2422.72	Pegatron	MK
9534T	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	2	5	..	*3099.62	Pegatron	MK

RIBAVIRIN and PEGINTERFERON ALFA-2b

Caution

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Caution

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Authority required (STREAMLINED)

3413

Patients naive to interferon based therapies (non-pegylated or pegylated)

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:
(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.
For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12).
Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24 hour access by patients to medical advice; and
(c) an established liver clinic; and
(d) facilities for safe liver biopsy.

Authority required (STREAMLINED)
3414
Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated)

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria:
(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.
The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24 hour access by patients to medical advice; and
(c) an established liver clinic; and
(d) facilities for safe liver biopsy.

9531P	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	2	5	..	*2707.66	Pegatron	MK
9536X	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent	2	5	..	*3491.58	Pegatron	MK
9538B	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	2	5	..	*4079.52	Pegatron	MK
9539C	Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	2	5	..	*4079.52	Pegatron	MK
9540D	Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	2	5	..	*4364.48	Pegatron	MK

Immunosuppressants

Immunosuppressants
Selective immunosuppressants

ABATACEPT
Note
Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

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AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with abatacept; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

5605B	Powder for I.V. infusion 250 mg	1	..	..	504.43	Orencia	BQ

EVEROLIMUS

Caution

Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required;

3356

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.

5737Y	Tablet 1 mg	240	5	..	*3844.80	Certican	NV
5738B	Tablet 0.25 mg	120	5	..	*480.60	Certican	NV
5739C	Tablet 0.5 mg	120	5	..	*961.20	Certican	NV

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	
5740D	Tablet 0.75 mg	240	5	..	*2883.60		Certican	NV

MYCOPHENOLATE MOFETIL

Caution

Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required;

3356

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.

9500B	Powder for oral suspension 1 g per 5 mL, 165 mL	2	5	..	*489.02		CellCept	RO
9501C	Capsule 250 mg	600	5	..	*933.54	a	APO-Mycophenolate	TX
						a	CellCept	RO
						a	Imulate	QA
						a	Mycophenolate Sandoz	SZ
						a	Pharmacor Mycophenolate 250	CR
				..	*933.60	a	Ceptolate	AF
9502D	Tablet 500 mg	300	5	..	*933.54	a	APO-Mycophenolate	TX
						a	CellCept	RO
						a	Ceptolate	AF
						a	Imulate	QA
						a	Mycophenolate Sandoz	SZ
						a	Pharmacor Mycophenolate 500	CR

MYCOPHENOLATE SODIUM

Caution

Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.

9503E	Tablet (enteric coated) 180 mg (mycophenolic acid)	240	5	..	*373.44		Myfortic	NV
9504F	Tablet (enteric coated) 360 mg (mycophenolic acid)	240	5	..	*746.86		Myfortic	NV

NATALIZUMAB

Caution

Progressive multifocal leukoencephalopathy has been reported with this drug.

Note

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Authority required (STREAMLINED)

3425

Treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the patient's medical notes, unless written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient is included in the patient's medical notes.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Natalizumab must be ceased if there is continuing progression of disability while on treatment with natalizumab. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, natalizumab.						
	Note Special Pricing Arrangements apply.						
9505G	Solution concentrate for I.V. infusion 300 mg in 15 mL	1	5	..	2038.46	Tysabri	BD
	SIROLIMUS						
	Caution Careful monitoring of patients is mandatory.						
	Authority required (STREAMLINED) ***3355*** Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.						
9548M	Tablet 2 mg	200	5	..	*2893.34	Rapamune	PF
9549N	Tablet 1 mg	200	5	..	*1446.66	Rapamune	PF
9550P	Oral solution 1 mg per mL, 60 mL	2	5	..	*936.00	Rapamune	PF
9747B	Tablet 0.5 mg	200	5	..	*723.34	Rapamune	PF

Tumor necrosis factor alpha (TNF-alpha) inhibitors

ADALIMUMAB

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:
(a) who has severe active juvenile idiopathic arthritis; AND
(b) whose parent or authorised guardian has signed a patient acknowledgement; AND
(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND
(d) who has demonstrated either:
(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or
(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:
— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with adalimumab by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has a documented history of severe active juvenile idiopathic arthritis; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required

Initial 3 ('grandfather' patients).

Initial PBS-subsidised supply for continuing treatment with adalimumab, by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has a documented history of severe active juvenile idiopathic arthritis; and
(b) was receiving treatment with adalimumab prior to 1 March 2010; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and
(d) is receiving treatment with adalimumab at the time of application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and (3) an acknowledgement signed by a parent or authorised guardian. A maximum of 24 weeks of treatment will be authorised under this restriction. At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The assessment of the patient's response to this initial course of PBS-subsidised therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment. A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. A patient may only qualify for PBS-subsidised treatment under this restriction once. **Authority required** Continuing treatment. Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient: (a) who has a documented history of severe active juvenile idiopathic arthritis; and (b) who has demonstrated an adequate response to treatment with adalimumab; and (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab. An adequate response to treatment is defined as: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or — shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of 24 weeks of treatment will be approved under this restriction. At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.						
9661L	Injection 20 mg in 0.4 mL pre-filled syringe	2	..	..	1630.00	Humira	AB
9662M	Injection 40 mg in 0.8 mL pre-filled syringe	2	..	..	1630.00	Humira	AB
9663N	Injection 40 mg in 0.8 mL pre-filled pen	2	..	..	1630.00	Humira	AB

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required
Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:

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(a) who has severe active juvenile idiopathic arthritis; AND
(b) whose parent or authorised guardian has signed a patient acknowledgement; AND
(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND
(d) who has demonstrated either:
(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or
(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:
— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required
Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with etanercept by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has a documented history of severe active juvenile idiopathic arthritis; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and
(c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare

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	Australia website (www.medicareaustralia.gov.au)].						
	Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.						
	A maximum of 16 weeks of treatment will be authorised under this restriction.						
	Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with etanercept may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.						
	Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.						
	If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.						
	Authority required Continuing treatment.						
	Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient: (a) who has a documented history of severe active juvenile idiopathic arthritis; and (b) who has demonstrated an adequate response to treatment with etanercept; and (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.						
	An adequate response to treatment is defined as: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following active joints, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or — shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).						
	The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].						
	A maximum of 24 weeks of treatment will be approved under this restriction.						
	Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.						
	If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.						
5734T	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	1	..	..	815.00	Enbrel	PF

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ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing

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their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required
Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre,

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	of a patient 18 years or older: (a) who has a documented history of severe active juvenile idiopathic arthritis; and (b) who has demonstrated an adequate response to treatment with etanercept; and (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept. An adequate response to treatment is defined as: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following active joints, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or — shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]. A maximum of 24 weeks of treatment will be approved under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. Where a patient with severe active juvenile idiopathic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed.						
5733R	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	..	..	1630.01	Enbrel	PF
5735W	Injection 50 mg in 1 mL single use auto-injector, 4	1	..	..	1630.01	Enbrel	PF

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required
Initial 2 (change or re-commencement for all patients)
Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with infliximab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required
Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	(a) has demonstrated an adequate response to treatment with infliximab; and (b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au]. All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with infliximab will be authorised under this criterion. At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone. All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with infliximab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.						
5753T	Powder for I.V. infusion 100 mg	1	..	..	751.70	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

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(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with infliximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with infliximab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note
Special Pricing Arrangements apply.

5757B	Powder for I.V. infusion 100 mg	1	..	..	751.70	Remicade	JC

INFLIXIMAB

Note
Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

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Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

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(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1
Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient,

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to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial 2

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with infliximab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and

(3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due

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to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent

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(Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
5756Y	Powder for I.V. infusion 100 mg	1	..	..	751.70	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or

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infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)
Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximb consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or
(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 1
Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 3 (grandfather)
Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or

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(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

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(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured. (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab. A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.						
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INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may

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commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or

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evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;
(ii) an 8 week course of enteral nutrition;
(iii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastoenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

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(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of moderate to severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:
(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and
(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

5755X	Powder for I.V. infusion 100 mg	1	..	..	751.70	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1
Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has an externally draining enterocutaneous or rectovaginal fistula; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required
Initial 2
Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:
(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) is receiving treatment with infliximab at the time of application; and
(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

9654D	Powder for I.V. infusion 100 mg	1	..	..	751.70	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

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(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Authority required
Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of

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treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. **Note** No applications for increased repeats will be authorised.						
5758C	Powder for I.V. infusion 100 mg	1	..	..	751.70	Remicade	JC

Interleukin inhibitors

TOCILIZUMAB

Note

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be

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documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with tocilizumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with tocilizumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats of each strength may be authorised.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. **Note** Special Pricing Arrangements apply.						
9657G	Concentrate for injection 80 mg in 4 mL	1	..	..	186.88	Actemra	RO
9658H	Concentrate for injection 200 mg in 10 mL	1	..	..	467.20	Actemra	RO
9659J	Concentrate for injection 400 mg in 20 mL	1	..	..	934.40	Actemra	RO

TOCILIZUMAB

Note

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:
— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

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(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with tocilizumab.

A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

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Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required

Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND
(b) has polyarticular course disease and either:
(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):
— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or
(ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR
(c) has refractory systemic symptoms, demonstrated by:
— an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND
(d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

(1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:
(a) in a patient with polyarticular course disease:
(i) an active joint count of at least 20 active (swollen and tender) joints; OR
(ii) at least 4 active joints from the following list:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
(b) in a patient with refractory systemic symptoms:
(i) an active joint count of at least 2 active joints; AND
(ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR
(iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

(2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.
Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.
If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.
If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
(ii) details of prior treatment including dose and duration of treatment;
(iii) pathology reports detailing CRP and platelet count where appropriate; and
(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Authority required

Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; AND
(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND
(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Authority required

Initial 3 ('grandfather' patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; and
(b) was receiving treatment with tocilizumab prior 1 November 2011; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and
(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) pathology reports detailing CRP and platelet count where appropriate; and
(3) a signed patient or authorised guardian acknowledgement form.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once.

Authority required
Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; AND
(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:
(a) in a patient with polyarticular course disease:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
(b) in a patient with refractory systemic symptoms:
(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR
(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR
(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	
	Monday to Friday). If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle. **Note** Special Pricing Arrangements apply.							
1476Q	Concentrate for injection 80 mg in 4 mL	1	..	..	186.88		Actemra	RO
1481Y	Concentrate for injection 200 mg in 10 mL	1	..	..	467.20		Actemra	RO
1482B	Concentrate for injection 400 mg in 20 mL	1	..	..	934.40		Actemra	RO

Calcineurin inhibitors

CYCLOSPORIN
Caution
Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)
3328
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required;

3329
Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate;

3330
Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life;

3331
Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired;

3332
Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate.

5632K	Capsule 10 mg	120	5	..	*74.40		Neoral 10	NV
5633L	Oral liquid 100 mg per mL, 50 mL	4	5	..	*1263.16		Neoral	NV
5634M	Capsule 25 mg	120	5	..	*153.56	[a]	Cicloral	SZ
						[a]	Neoral 25	NV
5635N	Capsule 50 mg	120	5	..	*319.52	[a]	Cicloral	SZ
				[B]4.24	*323.76	[a]	Neoral 50	NV
5636P	Capsule 100 mg	120	5	..	*651.08	[a]	Cicloral	SZ
				[B]5.56	*656.64	[a]	Neoral 100	NV

CYCLOSPORIN
Caution
Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)
3333
For use by organ or tissue transplant recipients.

5631J	Solution concentrate for I.V. infusion 50 mg in 1 mL	10	..	..	54.10		Sandimmun	NV

TACROLIMUS
Caution
Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)
3328
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
9558C	Capsule 0.5 mg	200	5	..	*327.84	[a] Prograf	JC
						[a] Tacrolimus Sandoz	SZ
9560E	Capsule 1 mg	200	5	..	*655.68	[a] Prograf	JC
						[a] Tacrolimus Sandoz	SZ
9561F	Capsule 5 mg	100	5	..	*1638.38	[a] Prograf	JC
						[a] Tacrolimus Sandoz	SZ
9664P	Capsule 0.5 mg (once daily prolonged release)	60	5	..	*98.36	Prograf XL	JC
9665Q	Capsule 1 mg (once daily prolonged release)	120	5	..	*393.40	Prograf XL	JC
9666R	Capsule 5 mg (once daily prolonged release)	60	5	..	*983.54	Prograf XL	JC

Other immunosuppressants

LENALIDOMIDE

Note

Any queries concerning the arrangements to prescribe lenalidomide may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Any queries concerning patients who are enrolled on the Lenalidomide Compassionate program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). These patients must demonstrate they met initial criteria prior to commencing treatment on the compassionate program and also demonstrate they do not have progressive disease. Baseline and current pathology reports must be submitted with the initial application.

Applications for authority to prescribe lenalidomide should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of a patient with a histological diagnosis of multiple myeloma who has progressive disease after at least 1 prior therapy and who has undergone or is ineligible for a primary stem cell transplant. The patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria.

Thalidomide treatment failure is defined as:
(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:
(1) less than a 25% reduction in serum or urine M protein; or
(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	free light chain levels. Lenalidomide will only be subsidised for patients with multiple myeloma who are not receiving concomitant PBS-subsidised bortezomib. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response. To enable confirmation by Medicare Australia, current diagnostic reports of at least one of the following are required: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria — the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (either previous or current serum M protein less than 10 g per L and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must be provided; and (3) duration of thalidomide and daily dose prescribed; and (4) a signed patient acknowledgment. **Note** Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. **Authority required** Continuing PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of multiple myeloma in a patient who has previously been issued with an authority prescription for lenalidomide and who does not have progressive disease. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Note** Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. **Note** Special Pricing Arrangements apply.							
5783J	Capsule 5 mg	21	..	..	5392.38	Revlimid	CJ
5784K	Capsule 10 mg	21	..	..	5643.33	Revlimid	CJ
5785L	Capsule 15 mg	21	..	..	6581.61	Revlimid	CJ
5786M	Capsule 25 mg	21	..	..	6934.20	Revlimid	CJ
	RITUXIMAB **Note** Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe rituximab should be forwarded to:							

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Initial 1 (patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and
(c) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(d) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date it was conducted.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and
(c) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with rituximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

A maximum of two infusions will be authorised under this restriction.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be provided to Medicare Australia no later than 4 weeks from the date of assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with rituximab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with rituximab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of two infusions will be authorised under this restriction.

Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

9544H	Solution for I.V. infusion 500 mg in 50 mL	1	..	..	2263.57	Mabthera	RO

THALIDOMIDE

Caution

Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Authority required (STREAMLINED)

3342

Multiple myeloma.

Note

Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

9566L	Capsule 50 mg	112	..	..	*1680.00	Thalomid	CJ
9667T	Capsule 100 mg	56	..	..	*1680.00	Thalomid	CJ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	

Musculo-skeletal system

Muscle relaxants

Muscle relaxants, centrally acting agents

Other centrally acting agents

BACLOFEN

Authority required (STREAMLINED)

3318

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin;

3319

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis;

3320

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury;

3321

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease.

5617P	Intrathecal injection 10 mg in 5 mL	10	..	..	*1483.70		Lioresal Intrathecal	NV

Drugs for treatment of bone diseases

Drugs affecting bone structure and mineralization

Bisphosphonates

DISODIUM PAMIDRONATE

Authority required (STREAMLINED)

3341

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 15 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 15 mg are equivalent for the purposes of substitution.

5667G	Concentrated injection 15 mg in 5 mL	4	2	..	*209.92	a	Pamisol	HH
5701C	Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL	1	2	..	209.91	a	Aredia 15 mg	NV

DISODIUM PAMIDRONATE

Authority required (STREAMLINED)

3341

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

5668H	Concentrated injection 30 mg in 10 mL	2	2	..	*209.92	a	Pamisol	HH
5702D	Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL	1	2	..	209.91	a	Aredia 30 mg	NV

DISODIUM PAMIDRONATE

Authority required (STREAMLINED)

3341

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

5669J	Concentrated injection 60 mg in 10 mL	1	2	..	209.90		Pamisol	HH

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	
	DISODIUM PAMIDRONATE							
	Authority required (STREAMLINED)							
	3341							
	Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.							
	Authority required (STREAMLINED)							
	3342							
	Multiple myeloma;							
	3343							
	Bone metastases from breast cancer.							
	Note							
	Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.							
5670K	Concentrated injection 90 mg in 10 mL	1	11	..	314.85	[a]	Pamisol	HH
5703E	Injection set containing 1 vial powder for I.V. infusion 90 mg and 1 ampoule solvent 10 mL	1	11	..	314.85	[a]	Aredia 90 mg	NV
	IBANDRONIC ACID							
	Authority required (STREAMLINED)							
	3343							
	Bone metastases from breast cancer.							
5750P	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	1	11	..	341.36		Bondronat	HH
	ZOLEDRONIC ACID							
	Authority required (STREAMLINED)							
	3342							
	Multiple myeloma;							
	3343							
	Bone metastases from breast cancer;							
	3882							
	Bone metastases from hormone-resistant prostate cancer;							
	3341							
	Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.							
	Note							
	Special Pricing Arrangements apply.							
9653C	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	1	11	..	450.00		Zometa	NV

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	

Nervous system

Anti-Parkinson drugs

Dopaminergic agents

Dopa and dopa derivatives

LEVODOPA with CARBIDOPA
Authority required (STREAMLINED)
3704
Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic.

Note
Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

9743T	Intestinal gel 20 mg-5 mg per mL, 100 mL	56	5	..	*11536.00		Duodopa	AB

Dopamine agonists

APOMORPHINE HYDROCHLORIDE
Authority required (STREAMLINED)
3314
Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy.

5609F	Injection 20 mg in 2 mL	5	..	..	77.86		Apomine	HH
5610G	Injection 50 mg in 5 mL	5	..	..	194.65		Apomine	HH
5611H	Solution for subcutaneous infusion 50 mg in 10 mL pre-filled syringe	5	..	..	194.65		Apomine PFS	HH

Psycholeptics

Antipsychotics

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE
Authority required (STREAMLINED)
3326
Schizophrenia in patients who are non-responsive to other neuroleptic agents;

3327
Schizophrenia in patients who are intolerant of other neuroleptic agents.

5626D	Tablet 50 mg	100	..	..	99.99		Clopine 50	HH
5627E	Tablet 200 mg	100	..	..	374.94		Clopine 200	HH
5628F	Tablet 25 mg	100	..	..	49.99	[a]	Clopine 25	HH
						[a]	Clozaril 25	NV
5629G	Tablet 100 mg	100	..	..	187.46	[a]	Clopine 100	HH
						[a]	Clozaril 100	NV
5630H	Oral liquid 50 mg per mL, 100 mL	1	..	..	135.00		Clopine Suspension	HH

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Respiratory system

Drugs for obstructive airway diseases

Other systemic drugs for obstructive airway diseases

Other systemic drugs for obstructive airway diseases

OMALIZUMAB

Note

Any queries concerning the arrangements to prescribe omalizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe omalizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

(2) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.

(5) Monitoring of patients.

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:
(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or
(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or
(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

(e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

(f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:
(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND
(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:
(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and
(iii) the signed patient acknowledgement; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.medicareaustralia.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:
(a) has a documented history of severe allergic asthma; and
(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

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The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

Authority required

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:
(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or
(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or
(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) past or current evidence of atopy, documented by skin prick testing or RAST; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and

(e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:
(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, and
(ii) may have included maintenance dose oral corticosteroids; and

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	(f) has demonstrated an adequate response to treatment with omalizumab. A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; (ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ); (iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or (iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab. Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and (iii) the signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks. An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment. Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment. Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. **Note** Special Pricing Arrangements apply.						
9745X	Powder for injection 150 mg with diluent	1	..	..	425.00	Xolair	NV

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer

Cough and cold preparations

Expectorants, excl. combinations with cough suppressants

Mucolytics

DORNASE ALFA

Authority required (STREAMLINED)

3344

Use by cystic fibrosis patients who satisfy all of the following criteria:
(1) are 5 years of age or older;
(2) have a FVC greater than 40% predicted for age, gender and height;
(3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);
(4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial.

In order for patients to be eligible for participation in the HSD program, the following conditions must be met:
(1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;
(2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;
(3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;
(4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily;
(5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily;
(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;
(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;
(8) Other aspects of treatment, such as physiotherapy, must be continued;
(9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period).

Note

It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.

Authority required (STREAMLINED)

3345

Treatment of cystic fibrosis in a patient less than 5 years of age who has:
(1) A severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring frequent hospital admissions more frequently than 3 times per year; or
(2) Significant bronchiectasis on chest high resolution computed tomography scan; or
(3) Severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or
(4) Severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

In order for the patient to be eligible for participation in the HSD program, the following conditions must be met:
(1) The patient must be assessed at a cystic fibrosis clinic/centre which is under the supervision of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis, and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;
(2) Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. Further reassessments are to be undertaken and documented yearly.

Note

It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.

Authority required (STREAMLINED)

3346

Grandfather — continuing for patients five years or older
Continuation of treatment of cystic fibrosis in a patient 5 years of age or older, who initiated treatment with dornase alfa at an age of less than 5

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	years and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.						
	Note It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.						
	Authority required (STREAMLINED) ***3347*** Grandfather — for patients less than five years of age who initiated dornase alfa prior to listing Treatment of cystic fibrosis in a patient less than 5 years of age who initiated treatment with dornase alfa prior to 1 November 2009 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.						
	Note It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.						
5704F	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	60	5	..	*2360.00	Pulmozyme	RO

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	

Sensory organs

Ophthalmologicals

Antiinfectives

Antivirals

GANCICLOVIR

Authority required (STREAMLINED)

3379

Cytomegalovirus retinitis in severely immunocompromised patients.

5748M	Intravitreal implant 4.5 mg	1	..	..	6000.00	Vitrasert	BU

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $		Brand Name and Manufacturer	

Various

All other therapeutic products

All other therapeutic products

Iron chelating agents

DEFERASIROX

Authority required (STREAMLINED)

3828

Chronic iron overload in patients with disorders of erythropoiesis.

Note

Special Pricing Arrangements apply.

5654N	Tablet 125 mg (dispersible)	168	5	..	*1401.48		Exjade	NV
5655P	Tablet 250 mg (dispersible)	168	5	..	*2802.90		Exjade	NV
5656Q	Tablet 500 mg (dispersible)	168	5	..	*5605.80		Exjade	NV

DEFERIPRONE

Authority required (STREAMLINED)

3338

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy;

3339

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective.

5657R	Tablet 500 mg	600	5	..	*2703.36		Ferriprox	OA
5658T	Oral solution 100 mg per mL, 250 mL	5	5	..	*1126.40		Ferriprox	OA

DESFERRIOXAMINE MESYLATE

Authority required (STREAMLINED)

3340

Disorders of erythropoiesis associated with treatment-related chronic iron overload.

5661Y	Powder for injection 2 g	60	5	..	*2235.00	a	Hospira Pty Limited	HH
				B22.80	*2257.80	a	Desferal 2 g	NV
5662B	Powder for injection 500 mg	400	5	..	*3725.60	a	Hospira Pty Limited	HH
				B308.80	*4034.40	a	Desferal 500 mg	NV

Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority required (STREAMLINED)

3390

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.
Management includes initiation, stabilisation and review of therapy as required;

3391

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.
Management includes initiation, stabilisation and review of therapy as required.

Note

Not to be used in combination with sevelamer.

5780F	Tablet, chewable, 500 mg (as carbonate hydrate)	180	5	..	*523.54		Fosrenol	ZI
5781G	Tablet, chewable, 750 mg (as carbonate hydrate)	180	5	..	*790.56		Fosrenol	ZI
5782H	Tablet, chewable, 1000 mg (as carbonate hydrate)	180	5	..	*890.02		Fosrenol	ZI

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	SEVELAMER HYDROCHLORIDE						
	Authority required (STREAMLINED)						
	3390						
	Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy. Management includes initiation, stabilisation and review of therapy as required;						
	3391						
	Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy. Management includes initiation, stabilisation and review of therapy as required.						
	Note						
	Not to be used in combination with lanthanum.						
9546K	Tablet 800 mg	360	5	..	*620.00	Renagel	GZ

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX				
	Note				
	Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.				
	Criteria for availability				
	Treatment of blepharospasm or hemifacial spasm in a patient 12 years or older;				
	Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive;				
	Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient;				
	Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care.				
	Criteria for availability				
	Treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient aged from 2 to 17 years inclusive;				
	Continuing PBS-subsidised treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.				
	Note				
	Contact Medicare Australia before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.				
	Criteria for availability				
	Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.				
	Criteria for availability				
	Treatment of severe primary axillary hyperhidrosis in a patient 12 years or older who has failed or is intolerant to topical aluminium chloride hexahydrate after one to two months of treatment. Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.				
	Note				
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.				
6103F	Lyophilised powder for injection 100 units	1	415.50	Botox	AG
	CLOSTRIDIUM BOTULINUM TYPE A TOXIN—HAEMAGGLUTININ COMPLEX				
	Note				
	Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.				
	Criteria for availability				
	Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive;				
	Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient;				
	Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care;				
	Treatment of blepharospasm or hemifacial spasm in an adult.				
	Criteria for availability				
	Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.				
	Note				
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.				
1152P	Lyophilised powder for I.M. injection 300 units	1	361.52	Dysport	IS
6293F	Lyophilised powder for I.M. injection 500 units	1	644.81	Dysport	IS

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer

SECTION 100 (HUMAN GROWTH HORMONE)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	SOMATROPIN (Recombinant human growth hormone)				
	Criteria for availability				
	Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.				
	The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:				
	(i) short stature and slow growth; (ii) short stature associated with biochemical growth hormone deficiency; (iii) growth retardation secondary to intracranial lesion or cranial irradiation; (iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency; (v) short stature associated with Turner Syndrome; (vi) short stature due to short stature homeobox (SHOX) gene disorders; (vii) short stature associated with chronic renal insufficiency; (viii) biochemical growth hormone deficiency and precocious puberty; (ix) Prader-Willi syndrome.				
	Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines.				
	Note				
	Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.				
	These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/hGH, or from: Growth Hormone Program Access and Systems Branch Department of Health and Ageing GPO Box 9848 CANBERRA ACT 2601 Contact telephone number (02) 6289 7274				
	Note				
	Special Pricing Arrangements apply.				
5818F	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	315.50	Norditropin FlexPro	NO
5819G	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	1	631.00	Norditropin FlexPro	NO
5820H	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	1	946.50	Norditropin FlexPro	NO
6465G	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	315.50	Norditropin NordiFlex	NO
6466H	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	1	631.00	Norditropin NordiFlex	NO
6467J	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	1	946.50	Norditropin NordiFlex	NO

SOMATROPIN (Recombinant human growth hormone)
Criteria for availability
Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.

The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:

(i) short stature and slow growth;
(ii) short stature associated with biochemical growth hormone deficiency;
(iii) growth retardation secondary to intracranial lesion or cranial irradiation;
(iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;
(v) short stature associated with Turner Syndrome;
(vi) short stature due to short stature homeobox (SHOX) gene disorders;
(vii) short stature associated with chronic renal insufficiency;
(viii) biochemical growth hormone deficiency and precocious puberty;
(ix) Prader-Willi syndrome.

Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines.

SECTION 100 (HUMAN GROWTH HORMONE)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	Note Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme. These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/hGH, or from: Growth Hormone Program Access and Systems Branch Department of Health and Ageing GPO Box 9848 CANBERRA ACT 2601 Contact telephone number (02) 6289 7274				
3388H	Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative)	1	990.00	Saizen	SG
5822K	Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	1	297.00	Saizen	SG
5824M	Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	1	594.00	Saizen	SG
6169Q	Injection 18 i.u. (6 mg) cartridge with 3.15 mL diluent (with preservative)	1	297.00	Humatrope	LY
6170R	Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with preservative)	1	594.00	Humatrope	LY
6266T	Injection 4 mg (12 i.u.) vial with diluent (with preservative)	1	198.00	Zomacton	FP
6295H	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	247.50	Norditropin SimpleXx	NO
6296J	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	1	495.00	Norditropin SimpleXx	NO
6297K	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	1	742.50	Norditropin SimpleXx	NO
6310D	Injection 10 mg (30 i.u.) vial with diluent (with preservative)	1	495.00	Zomacton	FP
6311E	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	1	495.00	Omnitrope	SZ
6312F	Injection 12 mg (36 i.u.) in 1 mL cartridge (with preservative)	1	594.00	Genotropin	PF
6313G	Injection 0.8 mg (2.4 i.u.) with diluent in single use syringe (without preservative)	7	277.20	Genotropin MiniQuick	PF
6314H	Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative)	7	346.50	Genotropin MiniQuick	PF
6315J	Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative)	7	415.80	Genotropin MiniQuick	PF
6316K	Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative)	7	485.10	Genotropin MiniQuick	PF
6317L	Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative)	7	554.40	Genotropin MiniQuick	PF
6318M	Injection 1.8 mg (5.4 i.u.) with diluent in single use syringe (without preservative)	7	623.70	Genotropin MiniQuick	PF
6319N	Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative)	7	693.00	Genotropin MiniQuick	PF
6329D	Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector)	1	396.00	Saizen 8 mg click.easy	SG
6330E	Injection 5 mg (15 i.u.) in 1 mL cartridge (with preservative)	1	247.50	Genotropin	PF
6345Y	Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative)	1	1188.00	Humatrope	LY
6476W	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	247.50	Omnitrope	SZ
9585L	Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative)	1	247.50	Genotropin GoQuick	PF
9586M	Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative)	1	594.00	Genotropin GoQuick	PF
9604L	Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)	1	495.00	NutropinAq	IS
9628R	Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative)	7	207.90	Genotropin MiniQuick	PF

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	CETRORELIX				
	Criteria for availability				
	For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
9599F	Powder for injection 250 micrograms (as acetate) with diluent	1	46.08	Cetrotide	SG
	CHORIOGONADOTROPIN ALFA				
	Criteria for availability				
	Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
	Note				
	Special Pricing Arrangements apply.				
6182J	Solution for injection 250 micrograms in 0.5 mL pre-filled pen	1	54.80	Ovidrel	SG
9631X	Solution for injection 250 micrograms in 0.5 mL pre-filled syringe	1	54.80	Ovidrel	SG
	CORIFOLLITROPIN ALFA				
	Criteria for availability				
	A patient who is receiving treatment as described in items 13200, 13201 or 13202 of the Medicare Benefits Schedule and who: (i) Has an antral follicle count of 20 or less; and (ii) Weighs 90 kg or less; and (iii) Is undergoing a gonadotrophin releasing hormone antagonist cycle.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
5816D	Solution for injection 100 micrograms in 0.5 mL single dose pre-filled syringe	1	410.14	Elonva	MK
5817E	Solution for injection 150 micrograms in 0.5 mL single dose pre-filled syringe	1	621.24	Elonva	MK
	FOLLITROPIN ALFA				
	Criteria for availability				
	Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
6431L	Injection 300 i.u. in 0.5 mL multi-dose cartridge	1	144.00	Gonal-f Pen	SG
6432M	Injection 450 i.u. in 0.75 mL multi-dose cartridge	1	216.00	Gonal-f Pen	SG
6433N	Injection 900 i.u. in 1.5 mL multi-dose cartridge	1	432.00	Gonal-f Pen	SG
	FOLLITROPIN BETA				
	Criteria for availability				
	Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
6335K	Solution for injection 300 i.u. in 0.36 mL multi-dose cartridge	1	144.04	Puregon 300 IU/0.36 mL	MK
6336L	Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge	1	288.09	Puregon 600 IU/0.72 mL	MK
6464F	Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge	1	432.11	Puregon 900 IU/1.08 mL	MK

SECTION 100 (IVF/GIFT TREATMENT)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	GANIRELIX				
	Criteria for availability				
	For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
9583J	Injection 250 micrograms (as acetate) in 0.5 mL pre-filled syringe	1	46.08	Orgalutran	MK
9584K	Injection 250 micrograms (as acetate) in 0.5 mL pre-filled syringe	5	230.40	Orgalutran	MK
	HUMAN CHORIONIC GONADOTROPHIN				
	Criteria for availability				
	Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
6178E	Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL	1	39.57	Pregnyl	MK
6181H	Powder for injection 5,000 units with solvent	1	11.49	Pregnyl	MK
	NAFARELIN				
	Criteria for availability				
	For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
5815C	Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses	1	75.33	Synarel	PF
	PROGESTERONE				
	Criteria for availability				
	For luteal phase support in patients who are receiving medical treatment as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
	Note				
	Special Pricing Arrangements apply.				
6366C	Vaginal gel (prolonged release) 90 mg in single dose pre-filled applicator	15	148.50	Crinone 8%	SG
	PROGESTERONE				
	Criteria for availability				
	For luteal phase support in patients who are receiving medical treatment as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
9608Q	Pessary 100 mg	15	50.40	Orion Laboratories Pty Ltd	ON
9609R	Pessary 200 mg	15	55.60	Orion Laboratories Pty Ltd	ON

SECTION 100 (OPIATE DEPENDENCE TREATMENT PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $		Brand Name and Manufacturer	
	BUPRENORPHINE					
	Criteria for availability					
	Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment.					
	Note					
	Treatment must be in accordance with the law of the relevant State or Territory.					
	Note					
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.					
6307Y *NP*	Tablet (sublingual) 400 micrograms (as hydrochloride)	7	6.16		Subutex	RC
6308B *NP*	Tablet (sublingual) 2 mg (as hydrochloride)	7	10.50		Subutex	RC
6309C *NP*	Tablet (sublingual) 8 mg (as hydrochloride)	7	30.10		Subutex	RC
	BUPRENORPHINE with NALOXONE					
	Caution					
	Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.					
	Criteria for availability					
	Treatment of opiate dependence within a framework of medical, social and psychological treatment.					
	Note					
	Treatment must be in accordance with the law of the relevant State or Territory.					
	Note					
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.					
6470M *NP*	Tablet (sublingual) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride)	28	46.20		Suboxone	RC
6471N *NP*	Tablet (sublingual) 8 mg (as hydrochloride)-2 mg (as hydrochloride)	28	132.44		Suboxone	RC
9749D *NP*	Film (soluble) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride)	28	46.20		Suboxone Film 2/0.5	RC
9750E *NP*	Film (soluble) 8 mg (as hydrochloride)-2 mg (as hydrochloride)	28	132.44		Suboxone Film 8/2	RC
	METHADONE HYDROCHLORIDE					
	Caution					
	The risk of drug dependence is high.					
	Criteria for availability					
	Treatment of opiate dependence in accordance with the law of the relevant State or Territory.					
	Note					
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.					
6171T *NP*	Oral liquid 25 mg per 5 mL, 200 mL	1	7.91	[a]	Biodone Forte	MW
				[a]	Sigma Methadone Syrup	QA
6172W *NP*	Oral liquid 25 mg per 5 mL, 1 L	1	33.20	[a]	Biodone Forte	MW
				[a]	Sigma Methadone Syrup	QA

Section 3 – Container Prices, Fees, Standard Packs and Prices for Ready Prepared Pharmaceutical Benefits

CONTAINER PRICES FOR QUANTITIES OF READY PREPARED BENEFITS LESS THAN THE STANDARD PACK:

Injectables	150 mL vial	$1.72
Other Items	25 mL vial	$0.72

(The 25 mL is the most commonly used size)

FEES:

Dispensing Fee for Ready Prepared Benefits	$6.42
Dangerous Drug Fee	$2.71
Additional Fee for Agreed Price Ready Prepared Benefits	$1.09

NOTE -

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 2 of the Schedule.

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
8048N	ABCIXIMAB	10 mg in 5 mL	1@	482.23	LY
1003T	ACICLOVIR	200 mg	25@	29.99	AF, SZ, GM
2600W	ALLOPURINOL	100 mg	100@	3.22	AF
2157M	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE	200 mg-200 mg per 5 mL, 500 mL	1@	5.64	JT
2159P	ALUMINIUM HYDROXIDE with MAGNESIUM TRISILICATE and MAGNESIUM HYDROXIDE	250 mg-120 mg-120 mg per 5 mL, 500 mL	1@	5.64	FM
3417W	AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS, and TRACE ELEMENTS, without METHIONINE and supplemented with DOCOSAHEXANOIC ACID	125 mL, 36	1@	625.39	SB
9330C	AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS without PHENYLALANINE and TYROSINE, and supplemented with DOCOSAHEXANOIC ACID	125 mL, 36	1@	625.39	SB
2347M	AMINO ACID FORMULA without PHENYLALANINE	20 g, 30	1@	208.07	SB
8554F		500 mg, 200	1@	79.37	SB
8678R		1 g, 75	1@	59.19	SB
8479G	AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE	400 g	1@	87.15	SB
2646G	AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN	500 g	1@	222.29	SB
2650L		400 g	1@	95.36	SB
5484P		25 g, 30	1@	787.00	VF
9438R		24 g, 30	1@	526.99	VF
8328H	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE	500 g	1@	222.29	SB
8416Y		500 g	1@	337.29	SB
8417B		400 g	1@	95.36	SB
8677Q		24 g, 30	1@	526.99	VF
8744F		25 g, 30	1@	772.99	VF
9133Q		130 mL, 30	1@	772.99	VF
3443F	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE	25 g, 30	1@	772.99	VF
3444G		24 g, 30	1@	526.99	VF
8058D		400 g	1@	95.36	SB
8059E		500 g	1@	222.29	SB
8061G		500 g	1@	337.29	SB
1411G	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE	18.2 g, 60	1@	544.55	SB
2382J		87 mL, 30	1@	257.09	VF
2474F		174 mL, 30	1@	511.90	VF
2738D		500 g	1@	109.70	SB
2739E		500 g	1@	168.25	SB
5483N		85 g, 30	1@	263.05	VF
8545R		400 g	1@	105.27	AB
8555G		24 g, 30	1@	263.05	VF
8591E		25 g, 30	1@	385.68	VF
8613H		29 g, 30	1@	221.42	SB
8727H		50 g, 30	1@	501.88	SB
8746H		250 mL	18@	261.37	SB
8804J		27.8 g, 30	1@	514.34	SB
8846N		130 mL, 30	1@	385.48	VF

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
9021T		125 mL, 30	1@	514.34	SB
9396M		125 mL, 36	1@	315.86	SB
9397N		62.5 mL, 60	1@	526.47	SB
3078B	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE	500 g	1@	337.29	SB
8445L		400 g	1@	95.36	SB
8446M		500 g	1@	222.29	SB
8631G		24 g, 30	1@	526.99	VF
8667E		25 g, 30	1@	772.99	VF
9132P		130 mL, 30	1@	772.99	VF
9395L		29 g, 30	1@	448.51	SB
2375B	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE	130 mL, 30	1@	772.99	VF
2380G		400 g	1@	95.36	SB
8057C		500 g	1@	337.29	SB
8260R		500 g	1@	222.29	SB
8310J		500 g	1@	666.39	SB
8592F		24 g, 30	1@	526.99	VF
8632H		25 g, 30	1@	772.99	VF
8745G		29 g, 30	1@	448.51	SB
9499Y	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE with FAT, CARBOHYDRATE and TRACE ELEMENTS and supplemented with DOCOSAHEXANOIC ACID	125 mL, 36	1@	625.39	SB
1180D	AMINO ACIDS—SYNTHETIC, FORMULA	400 g	1@	44.34	SB
1192R		400 g	1@	44.34	SB
2244D		400 g	1@	44.34	SB
2250K		400 g	1@	43.77	AB
2553J		400 g	1@	44.34	SB
8574G		400 g	1@	44.34	AB
8575H		400 g	1@	44.34	AB
8754R		400 g	1@	44.34	SB
8755T		400 g	1@	44.34	SB
2246F	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS	400 g	1@	45.18	SB
2560R		400 g	1@	45.18	SB
9339M		400 g	1@	45.18	AB
9340N		400 g	1@	45.18	AB
5466Q	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN TRIGLYCERIDES	400 g	1@	45.18	SB
5467R		400 g	1@	45.18	SB
8736T	AMISULPRIDE	100 mg per mL, 60 mL	1@	71.16	SW
9386B	AMYLOPECTIN, MODIFIED LONG CHAIN	60 g, 30	1@	186.47	VF
5482M	ARGININE with CARBOHYDRATE	4 g containing 2 g arginine, 30	1@	191.10	VF
9437Q		4 g containing 500 mg arginine, 30	1@	127.40	VF
9092M	ATOMOXETINE HYDROCHLORIDE	10 mg (base)	28@	107.38	LY
9093N		18 mg (base)	28@	107.38	LY
9094P		25 mg (base)	28@	107.38	LY
9095Q		40 mg (base)	28@	107.38	LY
9096R		60 mg (base)	28@	107.38	LY
1140B	BCG IMMUNOTHERAPEUTIC (Bacillus Calmette-Guérin/ Connaught strain)	6.6 to 19.2 x 10^8 CFU	1@	151.15	SW
1775K	BENZYLPENICILLIN	600 mg	1@	3.65	CS
2647H		3 g	1@	6.05	CS
3398W		600 mg	1@	3.65	CS
3399X		3 g	1@	6.05	CS
2812B	BETAMETHASONE VALERATE	200 mcg (base) per g, 100 g	1@	12.34	QA

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
2820K		200 mcg (base) per g, 100 g	1@	10.13	MK
2544X	BIPERIDEN HYDROCHLORIDE	2 mg	100@	7.23	LM
1258F	BISACODYL	10 mg, 12	1@	3.97	PP
1260H		10 mg, 10	1@	5.34	BY
5303D		10 mg, 10	1@	5.34	BY
5304E		10 mg, 12	1@	3.97	PP
5307H		10 mg, 10	1@	5.34	BY
5308J		10 mg, 12	1@	3.97	PP
1443Y	BROMOCRIPTINE MESYLATE	2.5 mg (base)	30@	12.50	NV
3116B	CALCIUM	500 mg	60@	6.01	IA
8740B	CALCIUM FOLINATE	equiv. to 50 mg folinic acid in 5 mL	1@	27.93	HH
8812T		equiv. to 100 mg folinic acid in 10 mL	1@	25.23	SZ
9041W		equiv. to 300 mg folinic acid in 30 mL	1@	73.02	HH, SZ
2419H	CARBAMAZEPINE	200 mg	100@	12.77	NV
2422L		100 mg	100@	7.52	NV
5039F		100 mg	100@	7.52	NV
5040G		200 mg	100@	12.77	NV
1153Q	CARBIMAZOLE	5 mg	100@	12.31	LM
8369L	CARBOHYDRATE, FAT, VITAMINS, MINERALS and TRACE ELEMENTS	400 g	1@	38.97	SB
8578L	CARBOMER	2 mg per g, 0.6 mL, 30	1@	9.89	NV
5504Q		2 mg per g, 0.6 mL, 30	1@	9.89	NV
8514D	CARBOMER 974	3 mg per g, 0.5 g, 30	1@	9.88	AQ
5502N		3 mg per g, 0.5 g, 30	1@	9.88	AQ
2324H	CARMELLOSE SODIUM	10 mg per mL, 0.4 mL, 30	1@	9.88	AG
2338C		5 mg per mL, 0.4 mL, 30	1@	9.88	AG
8823J		2.5 mg per mL, 0.6 mL, 24	1@	8.50	CX
8824K		10 mg per mL, 0.6 mL, 28	1@	9.22	CX
5505R		10 mg per mL, 0.4 mL, 30	1@	9.88	AG
5506T		5 mg per mL, 0.4 mL, 30	1@	9.88	AG
5509Y		2.5 mg per mL, 0.6 mL, 24	1@	8.50	CX
5510B		10 mg per mL, 0.6 mL, 28	1@	9.22	CX
9307W	CARMELLOSE SODIUM with GLYCERIN	5 mg-9 mg per mL, 0.4 mL, 30	1@	9.88	AG
5561Q		5 mg-9 mg per mL, 0.4 mL, 30	1@	9.88	AG
8315P	CEFEPIME	1 g	1@	15.52	BQ, OE, HH
8316Q		2 g	1@	28.68	BQ, OE, HH
1085D	CEFOTAXIME	1 g	1@	1.99	SZ
1086E		2 g	1@	3.65	SZ
5048Q		1 g	1@	1.99	SZ
5049R		2 g	1@	3.65	SZ
1783W	CEFTRIAXONE	500 mg	1@	3.83	PP
1784X		1 g	1@	5.98	RO, HH, SZ, PP
1785Y		2 g	1@	10.62	RO, HH, SZ, PP
1256D	CEPHAZOLIN	500 mg	5@	16.73	HH, AE
1257E		1 g	5@	25.25	HH, AE
5477G		500 mg	5@	16.73	HH, AE
5478H		1 g	5@	25.25	HH, AE
5479J		2 g	1@	9.78	SZ, AF
9326W		2 g	1@	9.78	SZ, AF
1163F	CHLORAMBUCIL	2 mg	25@	32.89	AS
1585K	CHLORTHALIDONE	25 mg	50@	5.58	LM
2967E	CHOLESTYRAMINE	4.7 g (equiv. to 4 g cholestyramine)	1@	32.76	QA
9249T		4.7 g (equivalent to 4 g cholestyramine)	1@	32.76	QA
1217C	CIPROFLOXACIN	3 mg per mL, 5 mL	1@	12.06	AQ
5564W		3 mg per mL, 5 mL	1@	12.06	AQ
5481L	CITRULLINE with CARBOHYDRATE	4 g containing 1 g citrulline, 30	1@	127.40	VF
1805B	CLONAZEPAM	500 mcg	100@	6.54	AF
1806C		2 mg	100@	12.32	AF
1808E		2.5 mg per mL, 10 mL	1@	4.31	RO
5339B		2.5 mg per mL, 10 mL	1@	4.31	RO
5342E		2.5 mg per mL, 10 mL	1@	4.31	RO
8785J	CODEINE PHOSPHATE with PARACETAMOL	30 mg-500 mg	20@	1.06	FM, AV, AL, SZ, TX
8657P	CYCLOSPORIN	10 mg	60@	44.00	NV

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
8658Q		25 mg	30@	45.41	NV, SZ
8659R		50 mg	30@	95.73	NV
8660T		100 mg	30@	185.51	NV
8661W		100 mg per mL, 50 mL	1@	353.12	NV
1270W	CYPROTERONE ACETATE	50 mg	50@	95.78	AF, GM, SY, GX, SZ
9164H	CYSTINE with CARBOHYDRATE	4 g containing 500 mg cystine, 30	1@	127.40	VF
9318K	DABIGATRAN ETEXILATE	75 mg (as mesilate)	10@	37.37	BY
9319L		110 mg (as mesilate)	10@	37.37	BY
9322P		75 mg (as mesilate)	10@	37.37	BY
9323Q		110 mg (as mesilate)	10@	37.37	BY
1229Q	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)	10,000 units (anti-Xa) in 1 mL	10@	84.57	PF
1296F		12,500 units (anti-Xa) in 0.5 mL	10@	117.43	PF
2816F		5,000 units (anti-Xa) in 0.2 mL	10@	51.23	PF
8603T		2,500 units (anti-Xa) in 0.2 mL	10@	49.16	PF
8641T		2,500 units (anti-Xa) in 0.2 mL	10@	49.16	PF
8642W		5,000 units (anti-Xa) in 0.2 mL	10@	51.23	PF
8643X		7,500 units (anti-Xa) in 0.75 mL	10@	61.96	PF
8956J		7,500 units (anti-Xa) in 0.75 mL	10@	61.96	PF
8957K		10,000 units (anti-Xa) in 1 mL	10@	82.88	PF
8958L		12,500 units (anti-Xa) in 0.5 mL	10@	114.43	PF
8959M		15,000 units (anti-Xa) in 0.6 mL	10@	136.11	PF
8960N		18,000 units (anti-Xa) in 0.72 mL	10@	162.39	PF
2129C	DESMOPRESSIN ACETATE	100 mcg per mL, 2.5 mL	1@	30.95	FP
8662X		200 mcg	30@	57.83	FP
8711L		10 mcg per actuation, 60 actuations, 6 mL	1@	77.31	FP
1299J	DICLOFENAC SODIUM	25 mg (e.c.)	50@	3.16	SZ, CH, TW, AF, QA, GM, TX
1302M		100 mg	20@	9.25	NV
5076E		25 mg (e.c.)	50@	3.16	SZ, CH, TW, AF, QA, GM, TX
5079H		100 mg	20@	9.25	NV
5361E		25 mg (e.c.)	50@	3.16	SZ, CH, TW, AF, QA, GM, TX
5363G		100 mg	20@	9.25	NV
5364H		25 mg (e.c.)	50@	3.16	SZ, CH, TW, AF, QA, GM, TX
5366K		100 mg	20@	9.25	NV
3164M	DIGOXIN	50 mcg per mL, 60 mL	1@	17.35	QA
8461H	DISODIUM PAMIDRONATE	15 mg in 5 mL	1@	60.93	HH
8462J		30 mg in 10 mL	1@	121.85	HH
2702F	DOXYCYCLINE	100 mg (as hydrochloride)	7@	1.94	GM, QA, AF
2703G		100 mg (as hydrochloride)	7@	1.94	YT
2714W		100 mg (as hydrochloride)	7@	1.94	GM, QA, AF
9107H		100 mg (as monohydrate)	7@	1.94	SZ, CH, TW, GX
9108J		100 mg (as monohydrate)	7@	1.94	SZ, CH, TW
3199J	ELECTROLYTE REPLACEMENT SOLUTION	1 L	1@	7.77	BX
5434B	ENOXAPARIN SODIUM	80 mg (8,000 i.u. anti-Xa) in 0.8 mL	10@	84.28	SW
5435C		100 mg (10,000 i.u. anti-Xa) in 1 mL	10@	102.33	SW
8510X		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10@	51.23	SW
8558K		20 mg (2,000 i.u. anti-Xa) in 0.2 mL	10@	49.16	SW
8639Q		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10@	51.23	SW
8640R		60 mg (6,000 i.u. anti-Xa) in 0.6 mL	10@	73.26	SW
8716R		20 mg (2,000 i.u. anti-Xa) in 0.2 mL	10@	49.16	SW
9195Y		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10@	51.23	SW
9196B		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10@	51.23	SW
8367J	ENTACAPONE	200 mg	100@	137.70	NV
8397Y	EPROSARTAN MESYLATE	400 mg (base)	28@	8.48	AB
8951D		400 mg (base)	28@	10.22	AB
8683B	EPTIFIBATIDE ACETATE	20 mg (base) in 10 mL	1@	128.06	MK
8684C		75 mg (base) in 100 mL	1@	337.98	MK
1397M	ERYTHROMYCIN LACTOBIONATE	1 g (base)	1@	18.44	LM

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack	Price $	Manufacturer
5088T		1 g (base)	1@	18.44	LM
9329B	ESSENTIAL AMINO ACIDS FORMULA	200 g	1@	199.02	SB
2027Q	ESSENTIAL AMINO ACIDS FORMULA with MINERALS and VITAMIN C	400 g	1@	125.55	SB
9385Y	ESSENTIAL AMINO ACIDS FORMULA with VITAMINS and MINERALS	12.5 g, 50	1@	377.52	VF
3445H	ETANERCEPT	25 mg and 1 mL solvent, 4	1@	911.29	PF
3448L		25 mg and 1 mL solvent, 4	1@	911.29	PF
8637N		25 mg and 1 mL solvent, 4	1@	911.29	PF
8638P		25 mg and 1 mL solvent, 4	1@	911.29	PF
8778B		25 mg and 1 mL solvent, 4	1@	911.29	PF
8779C		25 mg and 1 mL solvent, 4	1@	911.29	PF
9035M		25 mg and 1 mL solvent, 4	1@	911.29	PF
9036N		25 mg and 1 mL solvent, 4	1@	911.29	PF
9037P		25 mg and 1 mL solvent, 4	1@	911.29	PF
9429G		25 mg and 1 mL solvent, 4	1@	911.29	PF
8748K	ETHACRYNIC ACID	25 mg	100@	95.44	FK
8842J	EVEROLIMUS	0.75 mg	60@	786.10	NV
9352F		1 mg	60@	1031.17	NV
5401G	FENTANYL	200 mcg, 3	1@	35.49	OA
5402H		400 mcg, 3	1@	35.49	OA
5403J		600 mcg, 3	1@	35.49	OA
5404K		800 mcg, 3	1@	35.49	OA
5405L		1200 mcg, 3	1@	35.49	OA
5406M		1600 mcg, 3	1@	35.49	OA
5407N		200 mcg, 30	1@	335.50	OA
5408P		400 mcg, 30	1@	335.50	OA
5409Q		600 mcg, 30	1@	335.50	OA
5410R		800 mcg, 30	1@	335.50	OA
5411T		1200 mcg, 30	1@	335.50	OA
5412W		1600 mcg, 30	1@	335.50	OA
1473M	FLUCONAZOLE	100 mg in 50 mL	1@	15.83	PF, HX, SZ, AE
1474N		200 mg in 100 mL	1@	29.65	PF, HX, SZ, AE, BX
1433K	FLUDROCORTISONE ACETATE	100 mcg	100@	20.04	QA
1437P	FOLIC ACID	5 mg	100@	3.80	AF
2958Q		500 mcg	100@	3.68	AF
8713N	FOLLITROPIN ALFA	300 i.u.	1@	185.67	SG
8714P		450 i.u.	1@	278.50	SG
8715Q		900 i.u.	1@	554.41	SG
8565T	FOLLITROPIN BETA	300 i.u. in 0.36 mL	1@	185.67	MK
8566W		600 i.u. in 0.72 mL	1@	371.33	MK
8871X		900 i.u. in 1.08 mL	1@	554.40	MK
8775W	FONDAPARINUX SODIUM	2.5 mg in 0.5 mL	2@	37.05	GK
2414C	FRUSEMIDE	20 mg	50@	1.84	SW
8444K	GELATIN - SUCCINYLATED	20 g per 500 mL, 500 mL	1@	13.11	BR
2245E	GLUCOSE	278 mmol per L, 1 L	1@	3.28	BR, PK, BX
9444C		139 mmol per 500 mL, 500 mL	1@	2.29	BR, PK
9445D		278 mmol per 500 mL, 500 mL	1@	2.29	PK
9474P		69.5 mmol per 250 mL, 250 mL	1@	3.45	BR, PK
5005K		139 mmol per 500 mL, 500 mL	1@	2.29	BR, PK
5106R		278 mmol per L, 1 L	1@	3.28	BR, PK, BX
3106L	GLUCOSE and KETONE INDICATOR—URINE	Test strips, 50	1@	5.44	RD
3107M		Test strips, 50	1@	5.50	BN
9254C		Test strips, 50	1@	5.44	RD
9255D		Test strips, 50	1@	5.50	BN
2263D	GLUCOSE INDICATOR—BLOOD	Test strips, 50	1@	23.38	MS
2860M		Test strips, 50	1@	23.38	NA
2890D		Test strips, 50	1@	23.38	NA
2914J		Test strips, 50	1@	19.74	NA
3406G		Test strips, 50	1@	23.38	LB
3407H		Test strips, 50	1@	23.38	LB
3441D		Test strips, 50	1@	23.38	JJ
3442E		Test strips, 50	1@	23.38	JJ

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
5043K		Test Strips, 50	1@	23.38	RD
5053Y		Test strips, 50	1@	23.38	RD
5266E		Test strips, 50	1@	23.38	NX
5267F		Test strips, 50	1@	23.38	NX
5268G		Test strips, 50	1@	23.38	NX
5269H		Test strips, 50	1@	23.38	NX
8723D		Test strips, 50	1@	23.38	BR
8739Y		Test strips, 50	1@	23.38	RD
8749L		Test strips, 50	1@	23.38	OZ
8759B		Test strips, 50	1@	23.38	LB
8795X		Test strips, 50	1@	23.38	PX
8806L		Test strips, 51	1@	23.38	RD
8825L		Test strips, 50	1@	23.38	NX
9013J		Test strips, 50	1@	23.38	OZ
9193W		Test strips, 25	1@	11.69	PZ
9256E		Test strips, 25	1@	11.69	PZ
9261K		Test strips, 50	1@	23.38	OZ
9263M		Test strips, 50	1@	23.38	OZ
9265P		Test strips, 50	1@	23.38	BR
9267R		Test strips, 50	1@	23.38	MS
9268T		Test strips, 50	1@	23.38	NX
9274D		Test strips, 50	1@	23.38	RD
9275E		Test strips, 51	1@	23.38	RD
9276F		Test strips, 50	1@	23.38	NA
9277G		Test strips, 50	1@	23.38	NA
9278H		Test strips, 50	1@	23.38	LB
9279J		Test strips, 50	1@	19.74	NA
9281L		Test strips, 50	1@	23.38	PX
9297H		Test strips, 50	1@	23.38	QB
9298J		Test strips, 50	1@	23.38	QB
9324R		Test strips, 50	1@	23.38	HE
9325T		Test strips, 50	1@	23.38	HE
9471L		Test strips, 50	1@	23.38	EH
9472M		Test strips, 50	1@	23.38	EH
9485F		Test strips, 50	1@	23.38	OI
9486G		Test strips, 50	1@	23.38	OI
3104J	GLUCOSE INDICATOR—URINE	Test strips, 50	1@	6.70	BN
9253B		Test strips, 50	1@	6.70	BN
2555L	GLYCEROL	700 mg, 12	1@	4.35	PP
2556M		1.4 g, 12	1@	4.49	PP
2557N		2.8 g, 12	1@	4.66	PP
5311M		700 mg, 12	1@	4.35	PP
5312N		1.4 g, 12	1@	4.49	PP
5313P		2.8 g, 12	1@	4.66	PP
5314Q		700 mg, 12	1@	4.35	PP
5315R		1.4 g, 12	1@	4.49	PP
5316T		2.8 g, 12	1@	4.66	PP
8728J	GRANISETRON HYDROCHLORIDE	2 mg (base)	1@	26.28	HH
8729K		3 mg (base) in 3 mL	5@	91.62	PK
8730L		3 mg (base) in 3 mL	5@	91.62	PK
1076P	HEPARIN SODIUM	35,000 units in 35 mL	1@	22.68	HH
9446E	HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and low in PROTEIN and CARBOHYDRATE	300 g	1@	42.96	SB
1639G	HYDRALAZINE HYDROCHLORIDE	50 mg	100@	5.50	AF
1640H		25 mg	100@	4.54	AF
1486F	HYDROCHLOROTHIAZIDE with AMILORIDE HYDROCHLORIDE	50 mg-5 mg	50@	3.54	AS
1502C	HYDROCORTISONE ACETATE	21.1 g	1@	15.33	AS
1501B	HYDROCORTISONE SODIUM SUCCINATE	100 mg with 2 mL solvent	1@	5.05	PF
1510L		100 mg with 2 mL solvent	1@	5.05	PF
1511M		250 mg with 2 mL solvent	1@	8.72	PF
5118J		100 mg with 2 mL solvent	1@	5.05	PF
5119K		250 mg with 2 mL solvent	1@	8.72	PF

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
9487H	HYDROXYETHYL STARCH 130/0.4	30 g per 500 mL, 500 mL	1@	13.11	PK
5317W	HYOSCINE BUTYLBROMIDE	20 mg in 1 mL	5@	17.02	BY
5318X		20 mg in 1 mL	5@	17.02	BY
8299T	HYPROMELLOSE with DEXTRAN	3 mg-1 mg per mL, 0.4 mL, 28	1@	9.55	AQ
5521N		3 mg-1 mg per mL, 0.4 mL, 28	1@	9.55	AQ
3190X	IBUPROFEN	400 mg	30@	2.77	AB
5123P		400 mg	30@	2.77	AB
5368M		400 mg	30@	2.77	AB
5370P		400 mg	30@	2.77	AB
2446R	IDARUBICIN HYDROCHLORIDE	5 mg	1@	80.23	PF
2448W		10 mg	1@	148.40	PF
2454E	INDOMETHACIN	25 mg	50@	3.00	AF
2757D		100 mg	20@	8.04	AS
5126T		25 mg	50@	3.00	AF
5128X		100 mg	20@	8.04	AS
5377B		25 mg	50@	3.00	AF
5378C		100 mg	20@	8.04	AS
5379D		25 mg	50@	3.00	AF
5380E		100 mg	20@	8.04	AS
8435Y	INSULIN ASPART	100 units per mL, 3 mL, 5	1@	51.56	NO, NF
8571D		100 units per mL, 10 mL	1@	30.57	NO
8609D	INSULIN ASPART—INSULIN ASPART PROTAMINE SUSPENSION	100 units (30 units-70 units) per mL, 3 mL, 5	1@	51.56	NF, NO
9040T	INSULIN DETEMIR	100 units per mL, 3 mL, 5	1@	85.26	NF, NO
9039R	INSULIN GLARGINE	100 units per mL, 3 mL, 5	1@	85.26	SW, AV
1921D	INSULIN GLULISINE	100 units per mL, 3 mL, 5	1@	51.56	AV, SW
9224L		100 units per mL, 10 mL	1@	30.57	SW
1533Q	INSULIN ISOPHANE (N.P.H.)	100 units per mL, 10 mL	1@	25.48	LY, NO
1711C		100 units per mL, 10 mL	1@	33.12	AS
1761Q		100 units per mL, 3 mL, 5	1@	43.58	NO, NI, LY
8084L	INSULIN LISPRO	100 units per mL, 10 mL	1@	30.57	LY
8212F		100 units per mL, 3 mL, 5	1@	51.56	LY, KP
8390N	INSULIN LISPRO—INSULIN LISPRO PROTAMINE SUSPENSION	100 units (25 units-75 units) per mL, 3 mL, 5	1@	51.56	LY, KP
8874C		100 units (50 units-50 units) per mL, 3 mL, 5	1@	51.56	LY, KP
1531N	INSULIN NEUTRAL	100 units per mL, 10 mL	1@	25.48	NO, LY
1713E		100 units per mL, 10 mL	1@	33.12	AS
1762R		100 units per mL, 3 mL, 5	1@	43.58	NO, LY
1426C	INSULIN NEUTRAL—INSULIN ISOPHANE (N.P.H.), (MIXED) (Biphasic Isophane)	100 units (30 units-70 units) per mL, 10 mL	1@	25.48	LY
1763T		100 units (30 units-70 units) per mL, 3 mL, 5	1@	43.58	LY, NO, NI
2062M		100 units (50 units-50 units) per mL, 3 mL, 5	1@	43.58	NO
8180M	INTERFERON ALFA-2a	3,000,000 i.u. in 0.5 mL	1@	33.32	RO
8181N		3,000,000 i.u. in 0.5 mL	1@	33.32	RO
8182P		4,500,000 i.u. in 0.5 mL	1@	51.66	RO
8183Q		6,000,000 i.u. in 0.5 mL	1@	67.66	RO
8184R		9,000,000 i.u. in 0.5 mL	1@	99.94	RO
8551C		4,500,000 i.u. in 0.5 mL	1@	51.66	RO
8552D		6,000,000 i.u. in 0.5 mL	1@	67.66	RO
8553E		9,000,000 i.u. in 0.5 mL	1@	99.94	RO
8348J	INTERFERON ALFA-2b	18,000,000 i.u. in 1.2 mL	1@	199.87	MK
8476D		30,000,000 i.u. in 1.2 mL	1@	333.11	MK
8572E		18,000,000 i.u. in 1.2 mL	1@	199.87	MK
1542E	IPRATROPIUM BROMIDE	250 mcg (anhydrous) in 1 mL, 30	1@	14.66	AF, PF, QA, TX
8238N		500 mcg (anhydrous) in 1 mL, 30	1@	17.32	AF, PF, QA, TX
8671J		21 mcg per dose (200 doses)	1@	13.71	BY
9134R	ISOLEUCINE with CARBOHYDRATE	4 g containing 50 mg isoleucine, 30	1@	127.40	VF
9436P		4 g containing 1 g isoleucine, 30	1@	140.14	VF
2588F	ISOSORBIDE DINITRATE	5 mg	100@	4.07	QA
1588N	KETOPROFEN	100 mg	20@	9.44	SW
5139L		100 mg	20@	9.44	SW

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
5387M	LACTULOSE	3.34 g per 5 mL, 500 mL	1@	5.59	AF, GM, QA, GX, SZ
5388N		3.34 g per 5 mL, 500 mL	1@	5.59	AF, GM, QA, GX, SZ
9148L	LAPATINIB	250 mg (as ditosylate monohydrate)	70@	1690.52	GK
8970D	LEVODOPA with CARBIDOPA	20 mg-5 mg per mL, 100 mL	7@	1459.49	AB
8797B	LEVODOPA with CARBIDOPA and ENTACAPONE	50 mg-12.5 mg-200 mg	100@	152.73	NV
8798C		100 mg-25 mg-200 mg	100@	167.75	NV
8799D		150 mg-37.5 mg-200 mg	100@	182.77	NV
9292C		200 mg-50 mg-200 mg	100@	196.60	NV
9344T		75 mg-18.75 mg-200 mg	100@	159.35	NV
9345W		125 mg-31.25 mg-200 mg	100@	173.77	NV
8290H	LITHIUM CARBONATE	450 mg (s.r.)	100@	13.94	GK
8203R	LOSARTAN	50 mg	30@	10.71	AF
5389P	MACROGOL 3350	13.125 g, 30	1@	14.13	NE
5390Q		13.125 g, 30	1@	14.13	NE
5426N		510 g	1@	14.13	KY, ON, OY
5427P		510 g	1@	14.13	KY, ON, OY
1598D	MERCAPTOPURINE	50 mg	25@	61.38	AS
2214M	MESALAZINE	500 mg (p.r.)	100@	145.51	FP
3413P		1 g (p.r.)	60@	162.13	FP
8598M		500 mg	100@	145.51	OA
8616L		2 g in 60 mL, 7	1@	82.45	OA
8617M		4 g in 60 mL, 7	1@	109.87	OA
8731M		500 mg (e.c.)	100@	145.51	OA
8753Q		1 g in 100 mL, 7	1@	82.45	FP
8768L		80 g	1@	82.45	OA
2395C	METHOTREXATE	50 mg in 2 mL	1@	4.65	WQ
5423K	METHYLNALTREXONE	12 mg in 0.6 mL	1@	41.39	LM
2826R	METHYSERGIDE	1 mg	50@	19.27	LM
1638F	METRONIDAZOLE	500 mg in 100 mL	10@	37.54	HH
5154G		500 mg in 100 mL	10@	37.54	HH
9026C	MICONAZOLE NITRATE	20 mg per g, 15 g	1@	4.74	JT
2349P	MILK POWDER—LACTOSE FREE FORMULA	900 g	1@	16.50	NU
2350Q		900 g	1@	16.50	NU
8282X		900 g	1@	21.29	PF
8283Y		900 g	1@	21.29	PF
2357C	MILK POWDER—LACTOSE MODIFIED	900 g	1@	22.13	SJ
2358D		900 g	1@	22.13	SJ
3092R	MILK POWDER—SYNTHETIC	400 g	1@	46.87	SB
8630F	MILK PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE	225 g	1@	26.75	SB
8816B	MODAFINIL	100 mg	60@	170.28	CS
8649F	MYCOPHENOLATE MOFETIL	250 mg	100@	173.98	RO, QA, TX, SZ, CR
8650G		500 mg	50@	173.98	RO, QA, TX, SZ, AF, CR
1674D	NAPROXEN	250 mg	50@	3.46	AF
5176K		250 mg	50@	3.46	AF
5345H		250 mg	50@	3.46	AF
5349M		250 mg	50@	3.46	AF
8298R	NARATRIPTAN	2.5 mg (as hydrochloride)	2@	9.74	GK
9734H		2.5 mg (as hydrochloride)	2@	11.13	GK
9316H	NEBIVOLOL	1.25 mg (as hydrochloride)	28@	22.10	CS
1309X	NILOTINIB	150 mg (as hydrochloride monohydrate)	40@	1487.15	NV
9171Q		200 mg (as hydrochloride monohydrate)	40@	1955.24	NV
2732T	NITRAZEPAM	5 mg	25@	1.40	AF
5359C		5 mg	25@	1.40	AF
5360D		5 mg	25@	1.40	AF
1967M	NORETHISTERONE	350 mcg	1@	2.51	FZ, JC
2774B	NORETHISTERONE with ETHINYLOESTRADIOL	Tablet-Pack	1@	2.51	FZ
2775C		Tablet-Pack	1@	2.51	FZ
2776D		Tablet-Pack	1@	2.51	FZ

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
3179H	NORETHISTERONE with MESTRANOL	Tablet-Pack	1@	2.51	PF
1698J	NYSTATIN	100,000 units per g, 15 g	1@	6.07	FM
8383F	OFLOXACIN	3 mg per mL, 5 mL	1@	12.86	AG
5567B		3 mg per mL, 5 mL	1@	12.86	AG
9294E	OLANZAPINE	210 mg	1@	246.68	LY
9295F		300 mg	1@	401.42	LY
3134Y	OXAZEPAM	15 mg	25@	1.23	AF
3135B		30 mg	25@	1.23	TX, FM, AF
5371Q		15 mg	25@	1.23	AF
5372R		30 mg	25@	1.23	TX, FM, AF
5373T		15 mg	25@	1.23	AF
5374W		30 mg	25@	1.23	TX, FM, AF
8588B	OXCARBAZEPINE	60 mg per mL, 250 mL	1@	65.85	NV
5453B	PANCREATIC EXTRACT	20 g	1@	45.12	AB
5454C		20 g	1@	45.12	AB
8020D		not less than 10,000 BP units lipase activity	100@	35.45	AB
8021E		not less than 25,000 BP units lipase activity	100@	70.66	AB
9226N		not less than 10,000 BP units lipase activity	100@	35.45	AB
9227P		not less than 25,000 BP units lipase activity	100@	70.66	AB
9412J		not less than 40,000 BP units lipase activity	100@	111.77	AB
9413K		not less than 40,000 BP units lipase activity	100@	111.77	AB
8366H	PANCRELIPASE	not less than 25,000 BP units lipase activity	100@	65.74	TM
9229R		not less than 25,000 BP units lipase activity	100@	65.74	TM
8784H	PARACETAMOL	500 mg	100@	1.90	GM, YS, XS, SZ, YM, TX, GQ, SW, FM
8814X		665 mg (m.r.)	96@	5.11	GC
5224Y		500 mg	100@	1.90	GM, YS, XS, SZ, YM, TX, GQ, SW, FM
5319Y		500 mg, 24	1@	19.51	GC
5320B		500 mg, 24	1@	19.51	GC
5343F		665 mg (m.r.)	96@	5.11	GC
5344G		665 mg (m.r.)	96@	5.11	GC
1754H	PARAFFIN	3.5 g	1@	7.41	IQ
9217D		3.5 g	1@	7.41	IQ
5523Q		3.5 g	1@	7.41	IQ
1166J	PHENOXYBENZAMINE HYDROCHLORIDE	10 mg, 30	1@	66.16	GH
1703P	PHENOXYMETHYLPENICILLIN	250 mg	25@	2.45	QA
1787C		250 mg	25@	2.45	QA
3028J		500 mg	25@	3.62	QA
8976K		125 mg per 5 mL, 100 mL	1@	3.88	AE
8977L		250 mg per 5 mL, 100 mL	1@	5.16	AE
9143F		150 mg per 5 mL, 100 mL	1@	8.54	QA
3360W		250 mg	25@	2.45	QA
3361X		500 mg	25@	3.62	QA
5012T		150 mg per 5 mL, 100 mL	1@	8.54	QA
5024K		125 mg per 5 mL, 100 mL	1@	3.88	AE
5029Q		250 mg per 5 mL, 100 mL	1@	5.16	AE
9384X	PHENYLALANINE with CARBOHYDRATE	4 g containing 50 mg phenylalanine, 30	1@	127.40	VF
9493P	POLYETHYLENE GLYCOL 400	2.5 mg per mL, single dose units 0.4 mL, 20	1@	6.59	AO
5560P		2.5 mg per mL, single dose units 0.4 mL, 20	1@	6.59	AO
9170P	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL	4 mg-3 mg per mL, single dose units 0.8 mL, 28	1@	13.83	AQ
5532E		4 mg-3 mg per mL, single dose units 0.8 mL, 28	1@	13.83	AQ

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
2334W	POLYGELINE	17.5 g per 500 mL, 500 mL	1@	13.11	AE
9475Q	POLY-L-LACTIC ACID	150 mg	1@	220.02	SW
9476R		150 mg	1@	220.02	SW
2642C	POTASSIUM CHLORIDE	600 mg	100@	3.23	NM
1920C	PREDNISOLONE SODIUM PHOSPHATE	equiv. to 20 mg prednisolone in 100 mL	7@	51.23	QA
2554K		equiv. to 5 mg prednisolone, 10	1@	11.76	QA
1948M	PROMETHAZINE HYDROCHLORIDE	50 mg in 2 mL	5@	7.95	HH
3374N		50 mg in 2 mL	5@	7.95	HH
1953T	PROPANTHELINE BROMIDE	15 mg	100@	10.02	QA
1955X	PROPYLTHIOURACIL	50 mg	100@	21.61	PL
2676W	PROTEIN HYDROLYSATE FORMULA with MEDIUM CHAIN TRIGLYCERIDES	400 g	1@	20.69	NT
8259Q		450 g	1@	12.93	NU
2608G	PYRIDOSTIGMINE BROMIDE	180 mg (m.r.)	50@	71.40	VT
2724J		10 mg	50@	8.29	VT
1937Y	RANITIDINE HYDROCHLORIDE	150 mg (base), effervescent	30@	5.45	GK
8162N		150 mg (base) per 10 mL, 300 mL	1@	9.05	GK
8903N		150 mg (base), effervescent	30@	7.03	GK
8905Q		150 mg (base) per 10 mL, 300 mL	1@	10.15	GK
8780D	RISPERIDONE	25 mg	1@	135.34	JC
8781E		37.5 mg	1@	173.51	JC
8782F		50 mg	1@	211.28	JC
8787L		0.5 mg	20@	6.73	JC, TX
8788M		0.5 mg (orally disintegrating)	28@	11.29	JC
8790P		1 mg (orally disintegrating)	28@	21.89	JC
8792R		1 mg (orally disintegrating)	28@	21.89	JC
8794W		2 mg (orally disintegrating)	28@	43.41	JC
8869T		0.5 mg	20@	6.73	JC, TX
8870W		0.5 mg (orally disintegrating)	28@	11.29	JC
9075P		3 mg (orally disintegrating)	28@	64.50	JC
9076Q		4 mg (orally disintegrating)	28@	85.95	JC
9080X		2 mg (orally disintegrating)	28@	43.41	JC
9313E	RIZATRIPTAN	10 mg (as benzoate)	2@	9.35	MK
1099W	SALBUTAMOL SULFATE	200 mcg (base)	100@	4.82	GK
1103C		2 mg (base) per 5 mL, 150 mL	1@	7.89	GK
2000G		2.5 mg (base) in 2.5 mL, 30	1@	5.95	AF, GX, QA, CR, SZ, GM
2001H		5 mg (base) in 2.5 mL, 30	1@	6.28	AF, GX, QA, CR, SZ, GM
2003K		5 mg (base) per mL, 30 mL	1@	6.28	PF
8288F		100 mcg (base) per dose (200 doses)	1@	3.70	AL, IA, TX
8354Q		100 mcg (base) per dose (200 doses)	1@	16.09	IA
2995P	SALCATONIN	50 i.u. in 1 mL	5@	33.54	NV
2997R		100 i.u. in 1 mL	5@	51.57	NV
2014B	SODIUM ALGINATE with CALCIUM CARBONATE and SODIUM BICARBONATE	1 g-320 mg-534 mg in 20 mL, 500 mL	1@	4.13	RC
2260Y	SODIUM CHLORIDE	513 mmol per L, 1 L	1@	2.85	BX
2264E		154 mmol per L, 1 L	1@	1.90	BR, PK, BX
9392H		77 mmol per 500 mL, 500 mL	1@	1.32	BR, PK
9473N		38.5 mmol per 250 mL, 250 mL	1@	1.99	BR, PK
5021G		77 mmol per 500 mL, 500 mL	1@	1.32	BR, PK
5212H		154 mmol per L, 1 L	1@	1.90	BR, PK, BX
5213J		513 mmol per L, 1 L	1@	2.85	BX
2266G	SODIUM CHLORIDE COMPOUND	1 L	1@	5.90	BX
2278X	SODIUM CHLORIDE with GLUCOSE	39 mmol-69 mmol per 500 mL, 500 mL	1@	4.47	BX
2279Y		19 mmol-104 mmol per 500 mL, 500 mL	1@	4.47	BX
2281C		31 mmol-222 mmol per L, 1 L	1@	3.42	BX
5214K		31 mmol-222 mmol per L, 1 L	1@	3.42	BX
5215L		19 mmol-104 mmol per 500 mL, 500 mL	1@	4.47	BX
5216M		39 mmol-69 mmol per 500 mL, 500 mL	1@	4.47	BX
2286H	SODIUM LACTATE COMPOUND	1 L	1@	1.82	BR, PK, BX
9416N		500 mL	1@	1.28	BR, PK
2289L	SODIUM VALPROATE	200 mg (e.c.)	100@	11.75	AF, WA, SZ, QA

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
2290M		500 mg (e.c.)	100@	22.48	AF, WA, SZ, QA
2293Q		200 mg per 5 mL, 300 mL	1@	14.25	SW
2294R		100 mg	100@	12.79	SW
2295T		200 mg per 5 mL, 300 mL	1@	14.25	SW
9380Q	SORAFENIB	200 mg (as tosylate)	60@	3225.33	BN
2091C	SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE	3.125 g-450 mg-45 mg in 5 mL, 12	1@	12.93	JT, AE
5331N		3.125 g-450 mg-45 mg in 5 mL, 12	1@	12.93	JT, AE
5332P		3.125 g-450 mg-45 mg in 5 mL, 12	1@	12.93	JT, AE
9448G	SOY LECITHIN	10 mg per mL, 10 mL	1@	14.82	RB
5545W		10 mg per mL, 10 mL	1@	14.82	RB
8577K	SOY PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE	384 mL	1@	5.53	AB
2093E	SULFASALAZINE	500 mg	100@	21.93	PF
2096H		500 mg (e.c.)	100@	23.91	FZ
9208P		500 mg	100@	21.93	PF
9209Q		500 mg (e.c.)	100@	23.91	FZ
8144P	SUMATRIPTAN	50 mg (as succinate)	2@	9.90	GK
8885P		50 mg (as succinate) (fast disintegrating)	2@	8.98	GK
2110C	TAMOXIFEN CITRATE	20 mg (base)	30@	27.39	AP
2088X	TEMAZEPAM	10 mg	25@	1.04	FM, AF, TX
5375X		10 mg	25@	1.04	FM, AF, TX
5376Y		10 mg	25@	1.04	FM, AF, TX
8819E	TEMOZOLOMIDE	5 mg	5@	56.56	MK, QA, WQ
8820F		20 mg	5@	157.22	MK, QA, WQ
8821G		100 mg	5@	670.94	MK, QA, WQ
9361Q		140 mg	5@	916.44	MK, QA, WQ
9160D	TERBINAFINE	10 mg per g, 15 g	1@	15.47	NC
8098F	TESTOSTERONE	100 mg	1@	33.86	MK
8099G		200 mg	1@	67.71	MK
2832C	TETRACOSACTRIN	1 mg in 1 mL	1@	12.97	NV
8221Q	TIAGABINE HYDROCHLORIDE	5 mg (base)	50@	33.11	OA
8222R		10 mg (base)	50@	66.21	OA
8223T		15 mg (base)	50@	95.23	OA
1356J	TOBRAMYCIN SULFATE	80 mg (base) in 2 mL	5@	29.30	HH
8872Y		80 mg (base) in 2 mL (without preservative)	5@	29.30	PF
2117K	TRIAMCINOLONE ACETONIDE	200 mcg per g, 100 g	1@	3.99	FM
2118L		200 mcg per g, 100 g	1@	3.99	FM
9308X	TRIGLYCERIDES, LONG CHAIN with GLUCOSE POLYMER	250 mL, 18	1@	55.56	VF
9309Y		1 L, 6	1@	74.40	VF
3128P	TRIGLYCERIDES, MEDIUM CHAIN	500 mL	1@	22.98	SB
9327X		250 mL	1@	26.00	SB
3136C	TRIGLYCERIDES, MEDIUM CHAIN and LONG CHAIN with GLUCOSE POLYMER	400 g	1@	36.14	SB
8478F	TRIGLYCERIDES—MEDIUM CHAIN, FORMULA	400 g	1@	51.86	SB
8629E		420 g	1@	57.63	SB
9383W		16 g, 30	1@	61.80	VF
9165J	TYROSINE with CARBOHYDRATE	4 g containing 1 g tyrosine, 30	1@	127.40	VF
8448P	URSODEOXYCHOLIC ACID	250 mg	100@	183.09	OA
8133C	VALACICLOVIR	500 mg (as hydrochloride)	10@	49.68	GK, GM, QA, TX, CH, TW, GN, AF, SZ, NV, FZ
9135T	VALINE with CARBOHYDRATE	4 g containing 50 mg valine, 30	1@	127.40	VF
9434M		4 g containing 1 g valine, 30	1@	140.14	VF
2270L	VANCOMYCIN	1 g	1@	10.10	HH, SZ, AF, WQ
3113W		125 mg	20@	112.92	AS
3114X		250 mg	20@	216.82	AS
3130R		500 mg	1@	5.05	HH, AS, SZ, AF, WQ
3131T		500 mg	1@	5.05	HH, AS, SZ, AF, WQ
3323X		500 mg	1@	5.05	HH, AS, SZ, AF, WQ

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
9129L	VARENICLINE	1 mg (as tartrate)	56@	112.64	PF
9009E	VINORELBINE	20 mg (as tartrate)	1@	98.33	FB
9010F		30 mg (as tartrate)	1@	145.85	FB
9328Y	VITAMINS, MINERALS and TRACE ELEMENTS with CARBOHYDRATE	200 g	1@	64.00	SB
9382T	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE	100 g, 10	1@	164.35	VF
8587Y	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE	400 g	1@	66.22	SB
8266C	ZOLMITRIPTAN	2.5 mg	2@	9.71	AP
9736K		2.5 mg	2@	11.09	AP
9390F	ZONISAMIDE	100 mg	56@	43.52	SA

Section 4

Drug Tariff

Container Prices

Standard Formulae Preparations

Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Pharmaceutical Benefits

Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		$	$	$	$
Acacia Mucilage (by weight)	APF 15	0.01	0.08	0.65	5.80
Acacia, powdered	BP	0.02	0.13	1.06	9.45
Acetic Acid (6 per cent)	BP	0.01	0.02	0.14	1.23
Acetic Acid (33 per cent)	BP	0.01	0.06	0.49	4.36
Acetone (use as additive only)	BP	0.01	0.10	0.76	6.76
Alum	BP	0.02	0.17	1.35	12.01
Aluminium Acetate Solution	BP	0.02	0.16	1.24	11.04
Anise Water Concentrated 1 in 40 (use as additive only)	BP	0.01	0.06	0.50	4.40
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.02	0.19	1.72
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.13	1.02	8.18	72.69
Aspirin	BP	0.06	0.49	3.88	34.50
Belladonna Tincture	BP	0.08	0.62	4.92	43.70
Benzocaine	BP	0.06	0.51	4.08	36.25
Benzoic Acid	BP	0.04	0.32	2.57	22.84
Benzoic Acid Compound Ointment	APF	0.01	0.11	0.87	7.78
Benzoic Acid Solution	BP	0.01	0.10	0.77	6.85
Benzoin Compound Tincture	BP	0.03	0.24	1.95	17.32
Boric Acid (use as additive only)	BP	0.01	0.05	0.39	3.45
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.01	0.07	0.58	5.18
Calcium Hydroxide	BP	0.08	0.67	5.34	47.50
Calcium Hydroxide Solution	BP	0.01	0.02	0.14	1.21
Castor Oil (use as additive only)	BP	0.01	0.10	0.78	6.90
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.03	0.26	2.31
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.02	0.14	1.14	10.10
Chlorhexidine Acetate (use as additive only)	BP	0.55	4.42	35.34	314.13
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.03	0.21	1.68	14.96
Chloroform (use as additive only)	BP	0.07	0.59	4.69	41.67

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		$	$	$	$
Chloroform Spirit	BP	0.01	0.07	0.55	4.88
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.09	0.68	6.08
Citric Acid Monohydrate	BP	0.02	0.12	0.98	8.73
Coal Tar	BP	0.12	0.98	7.83	69.60
Coal Tar Solution	BP	0.02	0.13	1.00	8.86
Cocaine Hydrochloride	BP	6.18	49.43	395.41	3514.75
Coconut Oil	BP	0.01	0.10	0.80	7.16
Codeine Linctus	APF	0.01	0.06	0.45	3.98
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	1.49	11.91	95.31	847.16
Collodion Flexible	BP	0.15	1.23	9.86	87.60
Dithranol	BP	4.12	32.95	263.61	2343.22
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.07	0.58	5.12
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	0.89	7.09	56.70	504.00
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.03	0.23	2.05
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.03	0.27	2.36
Ether Solvent (use as additive only)	BP	0.15	1.16	9.26	82.35
Eucalyptus Oil (use as additive only)	BP	0.02	0.13	1.03	9.12
Ferrous Sulfate	BP	0.11	0.91	7.31	65.00
Formaldehyde Solution	BP	0.10	0.80	6.39	56.79
Gentian Alkaline Mixture	APF	0.01	0.07	0.57	5.03
Glycerol	BP	0.01	0.06	0.47	4.16
Honey Purified (use as additive only)	BP 1993	0.01	0.02	0.16	1.40
Hydroxybenzoate Compound Solution	APF	0.07	0.55	4.38	38.97
Iodine	BP	0.23	1.81	14.50	128.89
Iodine Alcoholic Solution	BP	0.02	0.13	1.07	9.48
Iodine Aqueous Oral Solution	BP	0.03	0.22	1.75	15.57
Kaolin Mixture	BPC 1968	0.01	0.10	0.78	6.90
Kaolin and Opium Mixture	APF 14	0.01	0.09	0.69	6.10
Lactic Acid	BP	0.06	0.49	3.91	34.74
Lavender Spike Oil	BPC 1968	0.09	0.71	5.71	50.75
Liquorice Liquid Extract	BP	0.03	0.25	1.99	17.70
Magnesium Carbonate Light	BP	0.03	0.23	1.80	16.00
Magnesium Sulfate	BP	0.01	0.01	0.08	0.73

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		$	$	$	$
(may only be prescribed for other than oral use)					
Magnesium Trisilicate	BP	0.04	0.29	2.35	20.89
Menthol, Racemic or Levomenthol	BP	0.24	1.91	15.24	135.46
Methyl Hydroxybenzoate	BP	0.30	2.40	19.22	170.84
Methyl Hydroxybenzoate Solution	APF	0.03	0.25	2.03	18.05
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.04	0.34	3.00
Olive Oil (use as additive only)	BP	0.02	0.12	0.94	8.33
Paraffin Hard	BP	0.01	0.05	0.43	3.82
Paraffin Liquid (may only be prescribed for other than oral use)	BP	0.01	0.03	0.24	2.16
Paraffin Light Liquid	BP	0.02	0.15	1.20	10.69
Paraffin Soft White	BP	0.01	0.04	0.34	3.02
Paraffin Soft Yellow	BP	0.01	0.06	0.48	4.28
Peppermint Oil (use as additive only)	BP	0.13	1.06	8.49	75.46
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.03	0.27	2.14	19.02
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	10.67	85.38	683.00	6071.11
Phenol Liquefied (not available for ear drops)	BP	0.17	1.37	10.94	97.20
Podophyllum Resin	BP	0.95	7.61	60.90	541.33
Potassium Citrate	BP	0.02	0.13	1.02	9.03
Potassium Iodide	BP	0.07	0.52	4.16	36.98
Potassium Permanganate	BP	0.03	0.23	1.85	16.40
Propyl Hydroxybenzoate	BP	0.25	2.02	16.12	143.29
Propylene Glycol	BP	0.01	0.09	0.68	6.04
Red Syrup	APF 15	0.02	0.13	1.07	9.50
Resorcinol	BP	0.28	2.23	17.81	158.31
Salicylic Acid	BP	0.03	0.22	1.74	15.49
Salicylic Acid Ointment	APF	0.02	0.12	0.92	8.18
Salicylic Acid Ointment	BP	0.02	0.12	0.92	8.18
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.15	1.20	10.63
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.16	1.31	11.65
Sodium Bicarbonate	BP	0.01	0.08	0.64	5.66

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		$	$	$	$
Sodium Chloride	BP	0.02	0.13	1.03	9.12
Sodium Chloride Solution	BP	0.01	0.01	0.08	0.67
Sodium Citrate	BP	0.02	0.15	1.18	10.45
Sodium Thiosulfate (use as additive only)	BP	0.03	0.21	1.67	14.87
Starch	BP	0.02	0.14	1.11	9.89
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.15	1.21	10.78
Sulfur Precipitated	BP 1980	0.02	0.15	1.21	10.79
Syrup	BP	0.01	0.05	0.36	3.23
Talc Purified, sterilised	BP	0.02	0.19	1.49	13.28
Thymol	BP	0.23	1.81	14.50	128.89
Thymol Compound Mouth Wash	APF 15	0.01	0.10	0.78	6.93
Tragacanth Compound Powder	BP 1980	0.08	0.63	5.05	44.93
Tragacanth Mucilage	APF 13	0.01	0.04	0.33	2.95
Tragacanth Mucilage	BPC 1973	0.01	0.03	0.22	1.98
Tragacanth, powdered	BP	0.12	0.95	7.59	67.50
Trichloroacetic Acid	BP 1980	0.32	2.59	20.74	184.33
Triethanolamine	BP	0.05	0.41	3.26	29.00
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	0.02	0.16	1.28	1.28
Water Purified	BP	0.01	0.01	0.06	0.54
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.15	10.19
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.15	10.19
Wool Fat	BP	0.02	0.14	1.14	10.17
Wool Fat Hydrous	BP	0.02	0.13	1.05	9.36
Zinc Compound Paste	BP	0.03	0.23	1.82	16.20
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.01	0.07	0.57	5.10
Zinc Oxide	BP	0.01	0.11	0.89	7.88
Zinc and Salicylic Acid Paste	BP	0.02	0.16	1.31	11.62
Zinc Sulfate	BP	0.03	0.21	1.67	14.87

Container Prices

Container Prices	
	$
DISPENSING BOTTLES –	
25mL	0.89
50mL	0.85
100mL	0.82
200mL	0.97
500mL	1.94
POISON BOTTLES –	
25mL	0.80
50mL	1.24
100mL	1.25
200mL	1.44
500mL	1.34
SCREW CAP JARS –	
25g	0.93
50g	1.05
100g	1.95
200g	0.89
500g	1.29
DROPPER CONTAINERS –	
15mL polythene	1.23
15mL glass	1.26
Dispensing Fee for Extemporaneously Prepared Benefits	**8.46**
Additional Fee for Agreed Price	**1.44**
Extemporaneously Prepared Benefits	

Standard Formula Preparations

The following list is not intended to indicate in any way which particular formula an approved pharmacist should use in filling a prescription.

The prices shown in the column 'Dispensed Price for Max. Qty' are for the ingredients, the container and the dispensing fee. The prices shown in the column 'Maximum Recordable Value for Safety Net' are for the ingredients, the container and the dispensing fee and, where applicable, the additional fee for agreed price benefits.

KEY TO REFERENCES:

APF Australian Pharmaceutical Formulary

BP British Pharmacopoeia

BPC British Pharmaceutical Codex

QHF Queensland Hospital Formulary

Standard Formula Preparations

Code	Item	Reference	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $
	CREAMS (Maximum Quantity 100 g and 1 Repeat)			
7502W	Salicylic Acid and Sulfur Aqueous	APF	12.80	14.24
	DUSTING POWDERS (Maximum Quantity 100 g and 1 Repeat)			
7458M	Zinc, Starch and Talc	APF 15 & BPC 1973	21.82	23.26
	EAR DROPS (Maximum Quantity 15 mL and 2 Repeats)			
7642F	Aluminium Acetate	APF	10.94	12.38
7643G	Aluminium Acetate	BP	11.55	12.99
7314Y	Sodium Bicarbonate	APF & BP	10.09	11.53
7313X	Spirit	APF	11.48	12.92
	INHALATIONS (Maximum Quantity 50 mL and 1 Repeat)			
7484X	Benzoin and Menthol	APF	21.35	22.79
7308P	Menthol	APF	12.76	14.20
7310R	Menthol and Eucalyptus	BP 1980	13.31	14.75
	LINCTUSES CONTAINING CODEINE PHOSPHATE (Maximum Quantity 100 mL and 0 Repeats)			
7530H	Codeine	APF	13.26	14.70
	LOTIONS (Maximum Quantity 200 mL and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	12.16	13.60
	MIXTURES, OTHER (Maximum Quantity 200 mL and 4 Repeats)			
7604F	Gentian Alkaline	APF	19.48	20.92
7348R	Kaolin	BPC 1968	23.22	24.66
7301G	Kaolin and Opium	APF 14	21.62	23.06
7342K	Magnesium Trisilicate	BPC 1968	16.61	18.05
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	21.41	22.85
	MOUTH WASHES (Maximum Quantity 200 mL and 1 Repeat)			
7457L	Thymol Compound	APF 15	23.75	25.19
	OINTMENTS (Maximum Quantity 100 g and 1 Repeat)			

Code	Item	Reference	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $
7914M	Benzoic Acid Compound	APF	18.19	19.63
7914M	Benzoic Acid Compound (extemporaneous formula)	BP	18.19	19.63
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	15.59	17.03
7926E	Salicylic Acid	APF	18.59	20.03
7928G	Salicylic Acid (extemporaneous formula)	BP	18.59	20.03
	PAINTS (Maximum Quantity 25 mL and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	42.68	34.20
7568H	Salicylic Acid	APF	34.44	34.20
	PASTES, OTHER (Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF	26.61	28.05
7558T	Zinc Compound (extemporaneous formula)	BP	26.61	28.05
	POWDER FOR INTERNAL USE (Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	30.24	31.68

Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 mL	2
19B	Eye Drops containing Cocaine Hydrochloride	15 mL	..
22E	Eye Drops, Other	15 mL	5
23F	Eye Lotions	200 mL	2
29M	Inhalations	50 mL	1
64J	Linctuses containing Codeine Phosphate	100 mL	..
34T	Linctuses, Other	100 mL	2
39C	Lotions	200 mL	2
65K	Mixtures containing Codeine Phosphate	200 mL	..
40D	Mixtures, Other	200 mL	4
66L	Mixtures for Children containing Codeine Phosphate	100 mL	..
41E	Mixtures for Children, Other	100 mL	4
30N	Mouth Washes	200 mL	1
42F	Nasal Instillations	15 mL	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 mL	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 mL	2

Special Note: Purified Water BP is the minimum requirement for water in all PBS extemporaneous preparations.

Australian Government

Department of Health and Ageing

REPATRIATION SCHEDULE OF PHARMACEUTICAL BENEFITS

1 June 2012

The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- Repatriation Health Card For All Conditions (gold); or
- Repatriation Health Card For Specific Conditions (white); or
- Repatriation Pharmaceutical Benefits Card (orange);

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

Gold card This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.	
White card A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with: • an accepted war or service-caused injury or disease; • malignant cancer (neoplasia) whether war-caused or not; • pulmonary tuberculosis whether war-caused or not; • post-traumatic stress disorder whether war-caused or not; or • anxiety and/or depression whether war-caused or not.	
Orange card Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who: • have qualifying service from World War I or II and • are aged 70 or over and • have been resident in Australia for 10 years or more.	

For more information go to the Department of Veterans' Affairs website:
http://www.dva.gov.au/service_providers/treatment_cards/Pages/index.aspx

RPBS Explanatory Notes

Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
    - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
    - the patient's full name and address;
    - the prescription date;
    - the DVA file number of the patient as evidence of entitlement;
    - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
    - the item, form, strength, quantity and directions;
    - the number of repeats, if applicable;
    - indicate when brand substitution is not permitted; and
    - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
    - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
    - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
    - items listed under section 100 of the *National Health Act 1953*; and
    - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
    - using the Department's national free call number 1800 552 580; or
    - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.
- Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.
- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
    - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
    - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
    - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
    - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.

  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.

- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

Palliative Care Drugs

The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:

  - clonazepam
  - cyclizine
  - dexamethasone
  - disodium pamidronate
  - fentanyl
  - glycopyrrolate
  - hyoscine butylbromide
  - hyoscine hydrobromide
  - ketamine
  - midazolam
  - octreotide

- For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled:
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

Payment for Items Supplied at Short Intervals

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are

required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

DEPARTMENT OF VETERANS' AFFAIRS

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterens' Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is:

1800 552 580

Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.

REPATRIATION PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 June 2012. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Deletions

Deletion – Brand

4237B *Fexal, SZ* – **Fexofenadine Hydrochloride**, Tablet 60 mg

4592Q *Gabahexal 300mg, SZ* – **Gabapentin**, Capsule 300 mg

4593R *Gabahexal 400mg, SZ* – **Gabapentin**, Capsule 400 mg

Deletion – Equivalence Indicator

4237B *Telfast, SW* – **Fexofenadine Hydrochloride**, Tablet 60 mg

Therapeutic Index for RPBS

Section 1

Drugs, Medicines and Dressings

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Alimentary tract and metabolism

Stomatological preparations

Stomatological preparations

Antiinfectives and antiseptics for local oral treatment

CHLORHEXIDINE GLUCONATE

4161B	Mouth wash 2 mg per mL (0.2%), 250 mL	‡1	..	..	11.89	5.80		Plaqacide	OB
4204G	Mouth wash 2 mg per mL (0.2%), 300 mL	‡1	..	..	15.28	5.80		Savacol Mouth and Throat Rinse	OM

Other agents for local oral treatment

CARMELLOSE SODIUM

4568K	Mouth spray 10 mg per mL, 25 mL	‡1	1	..	10.79	5.80		Aquae	VT
4569L	Mouth spray 10 mg per mL, 100 mL	‡1	..	..	12.46	5.80		Aquae	VT

Drugs for acid related disorders

Antacids

Calcium compounds

CALCIUM CARBONATE with GLYCINE

Note

For patients with chronic renal failure.

4055K	Tablet 420 mg-180 mg	200	5	..	*23.18	5.80		Titralac	MM

Combinations and complexes of aluminium, calcium and magnesium compounds

ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE

4118R	Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL	2	5	..	*22.64	5.80		Mylanta Double Strength	JT
4453J	Tablet 400 mg-400 mg-40 mg	200	5	..	*46.12	5.80		Mylanta Double Strength	JT

Drugs for functional gastrointestinal disorders

Drugs for functional bowel disorders

Synthetic anticholinergics, esters with tertiary amino group

MEBEVERINE HYDROCHLORIDE

4328T	Tablet 135 mg	90	..	..	26.91	5.80	[a]	Colese	AF
				..	32.09	5.80	[a]	Colofac	AB

Belladonna and derivatives, plain

Belladonna alkaloids semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

4279F	Injection 20 mg in 1 mL	5	..	..	24.21	5.80		Buscopan	BY

Laxatives

Laxatives

Softeners, emollients

DOCUSATE SODIUM

4200C	Tablet 50 mg	100	2	..	14.31	5.80		Coloxyl 50	FM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Contact laxatives							
	DOCUSATE SODIUM with SENNA							
4028B	Tablet 50 mg-8 mg	100	2	..	14.41	5.80	Soflax	GM
4198Y	Tablet 50 mg-8 mg	90	2	..	16.70	5.80	Coloxyl with Senna	FM
	SENNA STANDARDISED							
4455L	Tablet 7.5 mg	100	1	..	13.86	5.80	Senokot	RC
	Bulk producers							
	ISPAGHULA HUSK							
4285M	Sachets 3.5 g, 30	‡1	1	..	17.64	5.80	Fybogel	RC
	PSYLLIUM HYDROPHILIC MUCILLOID							
4419N	Oral powder (orange-flavoured, sugar-free) 283 g	‡1	1	..	21.67	5.80	Metamucil Smooth Texture Orange	PY
4422R	Oral powder (non-flavoured) 336 g	‡1	1	..	21.67	5.80	Fibre Health Natural Granular	PP
							Metamucil Regular	PY
	PSYLLIUM HYDROPHILIC MUCILLOID with HIGH AMYLOSE MAIZE STARCH							
4416K	Oral powder 2.7 g-0.7 g per 7.5 g, 440 g	‡1	1	..	21.27	5.80	Nucolox	QA
	STERCULIA with FRANGULA BARK							
4558X	Granules 620 mg-80 mg per g (62%-8%), 500 g	‡1	1	..	26.37	5.80	Normacol Plus	NE
	Enemas							
	SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE							
4462W	Enemas 3.125 g-450 mg-45 mg in 5 mL, 4	‡1	..	..	12.10	5.80	Micolette	AE
							Microlax	JT
	Other laxatives							
	GLYCEROL **Restricted benefit** Short-term use when oral laxative therapy has failed or is inappropriate.							
4246L	Suppositories 2.8 g (for adults), 12	3	..	..	*20.40	5.80	Petrus Pharmaceuticals Pty Ltd	PP

Antiobesity preparations, excl. diet products

Antiobesity preparations, excl. diet products

Peripherally acting antiobesity products

ORLISTAT
Authority required
For the treatment of obese patients.
Total treatment will not exceed 12 months from initial application.
Patients are eligible for 1 continuous treatment in a lifetime.
The patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Initial treatment for patients who meet the following criteria to qualify:
(a) Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; or
(b) BMI greater than or equal to 30 with 1 or more of the following co-morbidities:
(i) diabetes;
(ii) ischaemic heart disease;
(iii) psychiatric conditions;

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	(iv) hypertension. The prescriber must provide the following: (a) initial body weight; and (b) BMI. Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 3 months and up to 6 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 2.5 kg or 2.5% (whichever is the lesser). Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 6 months and up to 12 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 5 kg or 5% (whichever is the lesser). **Note** The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.							
4570M	Capsule 120 mg	84	2	..	140.16	5.80	Xenical	RO

Vitamins

Vitamin B_1, plain and in combination with vitamin B_6 and vitamin B_{12}

Vitamin B_1, plain

THIAMINE HYDROCHLORIDE

4043T	Tablet 100 mg	100	2	..	11.50	5.80	Betamin	SW

Vitamin B-complex, incl. combinations

Vitamin B-complex, plain

VITAMIN B GROUP COMPLEX

4493L	Oral liquid 200 mL	‡1	2	..	13.34	5.80	Accomin Adult Tonic	PF

Mineral supplements

Calcium

Calcium

CALCIUM
Restricted benefit
Hypocalcaemia;

Osteoporosis;

Proven calcium malabsorption.

4082W	Tablet 600 mg (as carbonate)	120	1	..	14.31	5.80	CAL-600	PP
4333C	Tablet (chewable) 500 mg (as carbonate)	120	1	..	*18.44	5.80	Cal-Sup	IA

CALCIUM
Restricted benefit
Hyperphosphataemia in chronic renal failure.

4094L	Tablet (chewable) 500 mg (as carbonate)	240	1	..	*30.46	5.80	Cal-Sup	IA
4142B	Tablet 600 mg (as carbonate)	240	1	..	*22.20	5.80	CAL-600	PP

Other mineral supplements

Magnesium

MAGNESIUM
Restricted benefit
Patients with documented hypomagnesaemia.

4321K	Tablet 37.4 mg (as aspartate dihydrate)	50	..	..	13.70	5.80	Mag-Sup	PP
				..	14.39	5.80	Magmin	BB

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Blood and blood forming organs

Antithrombotic agents

Antithrombotic agents

Platelet aggregation inhibitors excl. heparin

	ASPIRIN								
4076M	Tablet 100 mg (with glycine)	90	1	..	15.67	5.80		Cardiprin 100	RC
	ASPIRIN								
	Note								
	The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.								
4077N	Tablet 100 mg (enteric coated)	84	1	..	13.71	5.80		Cartia	GC
4078P	Capsule 100 mg (containing enteric coated pellets)	84	1	..	14.62	5.80		Astrix	YN
	CLOPIDOGREL								
	Authority required								
	For use in patients pre- and post-angioplasty.								
4179Y	Tablet 75 mg (as hydrogen sulfate)	28	3	..	50.05	5.80	[a]	Iscover	BQ
							[a]	Plavix	SW

Blood substitutes and perfusion solutions

Irrigating solutions

Salt solutions

	SODIUM CHLORIDE								
4460R	Irrigation solution 9 mg per mL (0.9%), 500 mL	‡1	2	..	10.33	5.80		Baxter Healthcare Pty Ltd	BX
4461T	Irrigation solution 9 mg per mL (0.9%), 1 L	‡1	2	..	10.65	5.80		Baxter Healthcare Pty Ltd	BX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Cardiovascular system

Vasoprotectives

Agents for treatment of hemorrhoids and anal fissures for topical use

Corticosteroids

HYDROCORTISONE with CINCHOCAINE HYDROCHLORIDE

Caution

Long-term use may lead to skin atrophy.

4036K	Ointment 5 mg-5 mg per g (0.5%-0.5%), 30 g	‡1	..	..	22.53	5.80	Proctosedyl	SW
4038M	Suppositories 5 mg-5 mg, 12	‡1	..	..	21.24	5.80	Proctosedyl	SW

Other agents for treatment of hemorrhoids and anal fissures for topical use

ZINC OXIDE

4039N	Compound ointment 50 g	‡1	1	..	14.44	5.80	Anusol	JT
4040P	Compound suppositories, 12	‡1	1	..	13.35	5.80	Anusol	JT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Dermatologicals							
	Antifungals for dermatological use							
	Antifungals for topical use							
	Antibiotics							
	NYSTATIN							
4001N	Cream 100,000 units per g, 15 g	‡1	1	..	12.49	5.80	Mycostatin	FM
	Imidazole and triazole derivatives							
	CLOTRIMAZOLE							
4004R	Cream 10 mg per g (1%), 20 g	‡1	1	..	8.84	5.80	Clonea	AF
	KETOCONAZOLE							
	Restricted benefit							
	Severe seborrhoeic dermatitis.							
4007X	Shampoo 20 mg per g (2%), 100 mL	‡1	..	..	19.37	5.80	Sebizole	GM
4008Y	Shampoo 20 mg per g (2%), 60 mL	‡1	..	..	18.31	5.80	Nizoral 2%	JT
	MICONAZOLE							
4341L	Tincture 20 mg per mL (2%), 30 mL	‡1	1	..	19.47	5.80	Daktarin	JT
	MICONAZOLE NITRATE							
3400Y	Cream 40 g (2% miconazole)	‡1	1	..	13.68	5.80	Resolve Thrush	EO
4454K	Cream 20 mg per g (2%), 30 g	‡1	1	..	14.79	5.80	Daktarin	JT
	Other antifungals for topical use							
	AMOROLFINE HYDROCHLORIDE							
	Restricted benefit							
	Onychomycosis.							
4010C	Nail treatment kit containing nail lacquer 50 mg (base) per mL (5%), 5 mL, 60 isopropyl alcohol cleaning pads, 10 spatulas and 30 nail files	‡1	1	..	96.14	5.80	Loceryl	GA
	CICLOPIROX OLAMINE							
	Restricted benefit							
	Severe seborrhoeic dermatitis.							
4106D	Shampoo 15 mg per g (1.5%), 60 mL	‡1	..	..	16.56	5.80	Stieprox Liquid	GK
	TERBINAFINE							
	Restricted benefit							
	Tinea pedis.							
4463X	Gel 10 mg per g (1%), 15 g	‡1	..	..	23.35	5.80	Lamisil DermGel	NC
4473K	Cream containing terbinafine hydrochloride 10 mg per g (1%), 15 g	‡1	1	..	21.89	5.80	Lamisil	NC
	TOLNAFTATE							
4481W	Spray aerosol 0.7 mg per g (0.07%), 100 g	‡1	..	..	15.09	5.80	Tinaderm	MK

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Antifungals for systemic use									
Antifungals for systemic use									
	TERBINAFINE								
	Authority required								
	Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider.								
4011D	Tablet 250 mg (as hydrochloride)	42	1	..	69.20	5.80	[a]	Lamisil (Novartis Pharmaceuticals Australia Pty Limited)	NV
							[a]	Tamsil	QA
							[a]	Terbihexal	SZ
							[a]	Terbinafine-DP	GN
							[a]	Tinasil	AF
Emollients and protectives									
Emollients and protectives									
Silicone products									
	DIMETHICONE with GLYCEROL								
	Restricted benefit								
	For colostomy and ileostomy use;								
	For use by paraplegic and quadriplegic patients;								
	For use with surgical appliances.								
4551M	Cream 150 mg-20 mg per g (15%-2%), 500 g	‡1	..	..	26.41	5.80		Silic 15	EO
4556T	Cream 150 mg-20 mg per g (15%-2%), 75 g	‡1	..	..	12.53	5.80		Silic 15	EO
Soft paraffin and fat products									
	WOOL ALCOHOLS								
4041Q	Ointment 100 g	‡1	1	..	14.18	5.80		Eucerin	BE
Carbamide products									
	UREA								
4042R	Cream 100 mg per g (10%), 100 g	‡1	2	..	12.19	5.80		Aquacare H.P.	AG
				..	12.45	5.80		Urederm	VT
				..	12.77	5.80		Calmurid	OL
Other emollients and protectives									
	CARMELLOSE SODIUM with PECTIN and GELATIN								
4518T	Paste 167 mg-167 mg-167 mg per g (16.7%-16.7%- 16.7%), 5 g	‡1	..	..	11.85	5.80		Orabase	QA
	SKIN EMOLLIENT								
4107E	Lotion 500 mL	‡1	2	..	17.35	5.80		Alpha Keri Lotion	MT
4122Y	Bath oil 500 mL	‡1	2	..	17.35	5.80		Alpha Keri Bath Oil	MT
				..	19.76	5.80		QV Bath Oil	EO
				..	19.85	5.80		Hamilton Skin Therapy Oil	VT
Protectives against UV-radiation									
Protectives against UV-radiation for topical use									
	SUNSCREENS								
4307Q	Cream 75 g	‡1	2	..	17.02	5.80		Sunsense Sensitive	EO

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							SPF 30+	
4543D	Solid stick 4.5 g	‡1	2	..	12.30	5.80	Hamilton Solastick 30+	VT
4544E	Cream 100 g	‡1	2	..	16.07	5.80	Hamilton Sunscreen Family Sunscreen Cream SPF 15	VT
4546G	Lotion (non-alcoholic) 125 mL	‡1	2	..	15.98	5.80	Aquasun Lotion SPF 18	PF
				..	16.07	5.80	Hamilton Sunscreen Family Sunscreen Milk SPF 15	VT
				..	16.99	5.80	SunSense Ultra SPF 30+	EO

Antipruritics, incl. antihistamines, anesthetics, etc.

Antipruritics, incl. antihistamines, anesthetics, etc.

Anesthetics for topical use

LIGNOCAINE HYDROCHLORIDE with CARBOXYMETHYLCELLULOSE

4308R	Mucilage 20 mg-25 mg per mL (2%-2.5%), 200 mL	‡1	..	..	79.35	5.80	Xylocaine Viscous	AP

Other antipruritics

PINE TAR with TRIETHANOLAMINE LAURYL SULFATE

Note

For patients who have failed to respond to simple moisturising agents.

4408B	Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL	‡1	2	..	22.92	5.80	Pinetarsol	EO

Antipsoriatics

Antipsoriatics for topical use

Tars

ALLANTOIN with SULFUR, PHENOL, COAL TAR SOLUTION and MENTHOL

4505D	Gel 25 mg-5 mg-5 mg-0.05 mL-7.5 mg per g (2.5%-0.5%-0.5%-5%-0.75%), 30 g	‡1	2	..	16.02	5.80	Egopsoryl-TA	EO

Antibiotics and chemotherapeutics for dermatological use

Antibiotics for topical use

Other antibiotics for topical use

MUPIROCIN

Restricted benefit

For the topical treatment of secondarily infected traumatic skin lesions.

4348W	Cream 20 mg (as calcium) per g (2%), 15 g	‡1	..	..	16.28	5.80	Bactroban	GK
4350Y	Ointment 20 mg per g (2%), 15 g	‡1	..	..	16.28	5.80	Bactroban	GK

Chemotherapeutics for topical use

Antivirals

PODOPHYLLOTOXIN

Authority required

For the treatment of ano-genital warts.

4390C	Cream 1.5 mg per g (0.15%), 5 g	‡1	..	..	52.66	5.80	Wartec Cream	GK

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
4566H	Paint 5 mg per mL (0.5%), 3.5 mL (with 30 swabs)	‡1	..	..	39.75	5.80	Condyline Paint	NQ

Corticosteroids, dermatological preparations

Corticosteroids, plain

Corticosteroids, potent (group III)

BETAMETHASONE VALERATE

4131K	Cream 1 mg (base) per g (0.1%), 30 g	‡1	2	..	22.43	5.80	Betnovate	QA
4132L	Ointment 1 mg (base) per g (0.1%), 30 g	‡1	2	..	22.43	5.80	Betnovate	QA

MOMETASONE FUROATE

Note

Application to large areas of skin for longer than four weeks is not recommended.

4342M	Cream 1 mg per g (0.1%), 50 g	‡1	..	..	30.78	5.80	Elocon	MK
4343N	Ointment 1 mg per g (0.1%), 50 g	‡1	..	..	30.78	5.80	Elocon	MK

Corticosteroids, combinations with antibiotics

Corticosteroids, moderately potent, combinations with antibiotics

TRIAMCINOLONE ACETONIDE with NEOMYCIN SULFATE, GRAMICIDIN and NYSTATIN

Caution

For the short-term treatment of localised infective eczema only.

4482X	Ointment 1 mg-2.5 mg (base)-250 micrograms-100,000 units per g (0.1%-0.25% (base)-0.025%- 100,000 units in 1 g), 15 g	‡1	..	..	19.09	5.80	Kenacomb	QA

Antiseptics and disinfectants

Antiseptics and disinfectants

Iodine products

POVIDONE-IODINE

4411E	Solution 100 mg per mL (10%), 100 mL	‡1	..	..	22.11	5.80	Betadine Antiseptic Liquid	SW

Other dermatological preparations

Other dermatological preparations

Antihidrotics

DIPHEMANIL METHYLSULFATE

4191N	Dusting powder 20 mg per g (2%), 50 g	‡1	1	..	17.74	5.80	Prantal	MK

Medicated shampoos

PINE TAR with CADE OIL, COAL TAR SOLUTION, ARACHIS OIL EXTRACT OF CRUDE COAL TAR and OLEYL ALCOHOL

4405W	Scalp cleanser 3 mg-3 mg-1 mg-3 mg-10 mg per mL (0.3%-0.3%-0.1%-0.3%-1%), 300 mL	‡1	2	..	21.03	5.80	Polytar	GK

SALICYLIC ACID with COAL TAR SOLUTION

4560B	Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL	‡1	2	..	20.38	5.80	Ionil-T	GA

SALICYLIC ACID with COAL TAR SOLUTION and PINE TAR

4447C	Scalp cleanser 20 mg-10 mg-10 mg per mL (2%-1%-1%), 250 mL	‡1	2	..	18.84	5.80	Sebitar	EO

Dermatologicals

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	SELENIUM SULFIDE							
4452H	Shampoo 25 mg per mL (2.5%), 125 mL	‡1	..	..	14.14	5.80	Selsun	DQ

Wart and anti-corn preparations

	SALICYLIC ACID							
4389B	Gel 270 mg per g (27%), 15 g	‡1	..	..	19.54	5.80	Duofilm Gel	GK
	SALICYLIC ACID with LACTIC ACID							
4386W	Liquid 167 mg-167 mg per g (16.7%-16.7%), 15 mL	‡1	..	..	18.15	5.80	Duofilm Solution	GK

Other dermatologicals

ALLANTOIN with GLYCEROL and ICHTHAMMOL

Note

For patients who have failed to respond to simple moisturising agents.

4280G	Ointment 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g	‡1	2	..	18.10	5.80	Egoderm Ointment	EO
4281H	Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g	‡1	2	..	18.10	5.80	Egoderm Cream	EO

CATIONIC CONDITIONER with PANTHENOL

Note

To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

4510J	Cream 200 g	‡1	2	..	14.25	5.80	SebiRinse	EO

DICLOFENAC SODIUM

Authority required

For the management of actinic keratoses in patients where other standard treatments are inappropriate, and topical drug therapy is required as field treatment for clinically visible and subclinical lesions.

Note

Maximum quantity of four tubes (original + 3 repeats) in 12 months.

4046Y	Gel 30 mg per g (3%), 25 g	‡1	3	..	58.19	5.80	Solaraze 3% Gel	CS

IMIQUIMOD

Authority required

Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required.

4559Y	Cream 50 mg per g (5%), 250 mg single use sachets, 12	1	1	..	159.95	5.80	Aldara	IA

IMIQUIMOD

Authority required

Treatment of solar keratosis on the face and scalp in patients where other standard treatments are inappropriate and topical drug therapy is required as field treatment for clinically visible and subclinical lesions.

4134N	Cream 50 mg per g (5%), 250 mg single use sachets, 12	1	1	..	159.95	5.80	Aldara	IA
	SKIN CLEANSER							
4549K	Lotion 500 mL	‡1	2	..	20.74	5.80	Hamilton Skin Therapy Wash	VT
	ZINC OXIDE with STARCH and CHLORPHENESIN							
4497Q	Dusting powder 100 g	‡1	1	..	12.26	5.80	Z.S.C.	QA

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Genito urinary system and sex hormones

Gynecological antiinfectives and antiseptics

Antiinfectives and antiseptics, excl. comb. with corticosteroids

Antibiotics

NYSTATIN

4013F	Vaginal cream 100,000 units per dose, 15 doses, 75 g	‡1	1	..	13.79	5.80	Nilstat	QA

Imidazole derivatives

CLOTRIMAZOLE

4016J	Vaginal cream 50 mg per 5 g (1%), 35 g	‡1	..	..	15.08	5.80	APO-Clotrimazole 6 Day Cream	TX
4017K	Vaginal cream 100 mg per 5 g (2%), 20 g	‡1	..	..	15.08	5.80	APO-Clotrimazole 3 Day Cream	TX

Other gynecologicals

Other gynecologicals

RICINOLEIC ACID with ACETIC ACID and HYDROXYQUINOLINE SULFATE

4434J	Vaginal jelly 7 mg-9.4 mg-250 micrograms per g (0.7%-0.94%-0.025%), 100 g	‡1	..	..	32.90	5.80	Aci-Jel	CU

Urologicals

Other urologicals, incl. antispasmodics

Drugs used in erectile dysfunction

ALPROSTADIL

Authority required

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

4579B	Intracavernosal injection 10 micrograms with diluent in single use syringe	6	3	..	*82.62	5.80	Caverject Impulse	PF
4580C	Intracavernosal injection 20 micrograms with diluent in single use syringe	6	3	..	*103.62	5.80	Caverject Impulse	PF

SILDENAFIL CITRATE

Authority required

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

4584G	Tablet 25 mg (base)	4	5	..	60.68	5.80	Viagra	PF
4585H	Tablet 50 mg (base)	4	5	..	75.49	5.80	Viagra	PF
4586J	Tablet 100 mg (base)	4	5	..	81.12	5.80	Viagra	PF

TADALAFIL

Note

Any queries concerning the arrangements to prescribe tadalafil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Genito urinary system and sex hormones

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
(c) epoprostenol sodium, of:
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

Genito urinary system and sex hormones

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Note

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.
All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:
Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.
For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.
Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required
Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

4596X	Tablet 10 mg	4	5	..	79.69	5.80	Cialis	LY
4597Y	Tablet 20 mg	4	5	..	83.26	5.80	Cialis	LY

VARDENAFIL
Authority required
Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

4290T	Tablet 10 mg	4	5	..	72.79	5.80	Levitra	BN
4302K	Tablet 20 mg	4	5	..	83.52	5.80	Levitra	BN

Other urologicals

SODIUM CITRO-TARTRATE
Restricted benefit
For relief of urinary symptoms when antibiotic or other therapy alone is inappropriate.

4049D	Sachets containing oral effervescent powder 4 g, 28	‡1	4	..	13.55	5.80	Uracol	GM
							Ural Sachets	QA

Genito urinary system and sex hormones

Drugs used in benign prostatic hypertrophy

Alpha-adrenoreceptor antagonists

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ALFUZOSIN HYDROCHLORIDE								
	Authority required								
	Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.								
4277D	Tablet 10 mg	30	5	..	63.36	5.80		Xatral SR	SW
	TAMSULOSIN HYDROCHLORIDE								
	Authority required								
	Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.								
4070F	Tablet 400 micrograms (prolonged release)	30	5	..	63.36	5.80		Flomaxtra	CS
	TERAZOSIN HYDROCHLORIDE								
	Authority required								
	Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.								
4396J	Starter pack containing 7 tablets 1 mg and 7 tablets 2 mg	‡1	..	..	20.05	5.80		Hytrin	AB
4397K	Tablet 2 mg	28	5	..	41.69	5.80		Hytrin	AB
4398L	Tablet 5 mg	28	5	..	58.19	5.80		Hytrin	AB
4399M	Tablet 10 mg	28	5	..	86.06	5.80		Hytrin	AB

Testosterone-5-alpha reductase inhibitors

	FINASTERIDE								
	Authority required								
	Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.								
4233T	Tablet 5 mg	30	5	..	102.12	5.80	[a]	Finasta	SZ
				..	111.69	5.80	[a]	Proscar	MK
4303L	Tablet 5 mg	28	5	..	91.27	5.80		Finpro	RZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Antiinfectives for systemic use

Antibacterials for systemic use

Macrolides, lincosamides and streptogramins

Macrolides

AZITHROMYCIN

Restricted benefit

Upper and lower respiratory tract infections.

4115N	Tablet 500 mg (as dihydrate)	3	..	..	31.51	5.80	Zedd 500	QA
							Zithromax	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Antineoplastic and immunomodulating agents

Antineoplastic agents

Antimetabolites

Pyrimidine analogues

FLUOROURACIL

4222F	Cream 50 mg per g (5%), 20 g	‡1	..	..	55.31	5.80	Efudix	VT

Immunosuppressants

Immunosuppressants

Tumor necrosis factor alpha (TNF-alpha) inhibitors

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998
Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001.

Authority required

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:
(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;
(2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
(3) No history of active tuberculosis requiring treatment in the last 3 years;
(4) No history of opportunistic infection in the last 2 months;
(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

Authority required

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:
(1) There is improvement in ESR and/or CRP; and
(2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998
Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans' Affairs

Antineoplastic and immunomodulating agents

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	GPO Box 9998 BRISBANE QLD 4001.							
4284L	Powder for I.V. infusion 100 mg	1	2	..	846.98	5.80	Remicade	JC

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Musculo-skeletal system

Antiinflammatory and antirheumatic products

Antiinflammatory and antirheumatic products, non-steroids

Acetic acid derivatives and related substances

DICLOFENAC SODIUM with MISOPROSTOL

Authority required

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease.

4190M	Tablet 50 mg-200 micrograms	60	2	..	37.78	5.80		Arthrotec 50	PF

Topical products for joint and muscular pain

Topical products for joint and muscular pain

Preparations with salicylic acid derivatives

METHYL SALICYLATE

4022Q	Compound cream APF, 100 g	‡1	1	..	14.02	5.80		Gold Cross	BI
4023R	Ointment BP, 100 g	‡1	1	..	12.17	5.80		Gold Cross	BI
4026X	Liniment APF, 100 mL	‡1	1	..	9.94	5.80		Gold Cross	BI

Drugs for treatment of bone diseases

Drugs affecting bone structure and mineralization

Bisphosphonates

RISEDRONATE SODIUM

Authority required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).

4443W	Tablet 5 mg	28	5	..	46.55	5.80		Actonel	SW
4444X	Tablet 35 mg	4	5	..	46.55	5.80	[a]	Actonel Once-a-Week	SW
							[a]	APO-Risedronate	TX
							[a]	Chem mart Risedronate	CH
							[a]	Risedro once a week	QA
							[a]	Terry White Chemists Risedronate	TW

Bisphosphonates, combinations

RISEDRONATE SODIUM and CALCIUM CARBONATE

Authority required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).

4059P	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	‡1	5	..	46.55	5.80		Actonel Combi	SW

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL

Authority required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day.

Musculo-skeletal system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density T-score of less than -1.0).							
4380M	Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms	‡1	5	..	46.55	5.80	Actonel Combi D	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

Nervous system

Analgesics

Opioids

Natural opium alkaloids

MORPHINE SULFATE

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for
(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

4349X	Tablet 200 mg (controlled release)	28	..	..	121.86	5.80		MS Contin	MF

Other analgesics and antipyretics

Salicylic acid and derivatives

CODEINE PHOSPHATE with ASPIRIN

4061R	Tablet soluble 8 mg-300 mg	50	2	..	13.57	5.80		Aspalgin	FM
4286N	Tablet 8 mg-300 mg	40	2	..	14.18	5.80		Aspalgin 40	QA

Anilides

CODEINE PHOSPHATE with PARACETAMOL

4170L	Tablet 15 mg-500 mg	20	2	..	9.73	5.80		Prodeine 15	SW
4171M	Tablet 8 mg-500 mg	50	2	..	12.86	5.80		Codalgin	FM
4275B	Tablet 8 mg-500 mg	40	2	..	10.69	5.80		Panamax Co. 40	SW

Other analgesics and antipyretics

GABAPENTIN

Authority required

To be approved for the treatment of refractory neuropathic pain not controlled by other drugs.

4591P	Capsule 100 mg	100	5	..	18.18	5.80	[a]	Gabatine 100	QA
							[a]	Nupentin 100	AF
				..	18.86	5.80	[a]	Neurontin	PF
4592Q	Capsule 300 mg	100	5	..	45.09	5.80	[a]	DBL Gabapentin	HH
							[a]	Gabatine 300	QA
							[a]	Gantin	GN
							[a]	GenRx Gabapentin	GX
							[a]	Nupentin 300	AF
				..	45.70	5.80	[a]	Neurontin	PF
4593R	Capsule 400 mg	100	5	..	57.68	5.80	[a]	DBL Gabapentin	HH
							[a]	Gabatine 400	QA
							[a]	Gantin	GN
							[a]	GenRx Gabapentin	GX
							[a]	Nupentin 400	AF
				..	58.36	5.80	[a]	Neurontin	PF
4594T	Tablet 600 mg	100	5	..	87.79	5.80	[a]	Gabatine 600	QA
				..	88.47	5.80		Neurontin	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
4595W	Tablet 800 mg	100	5	..	114.90	5.80	a	Gabatine 800	QA
							a	Gantin	GN
				..	115.57	5.80	a	Neurontin	PF
	PREGABALIN **Authority required** For the treatment of refractory neuropathic pain not controlled by other drugs.								
4320J	Capsule 25 mg	56	5	..	42.65	5.80		Lyrica	PF
4322L	Capsule 75 mg	56	5	..	84.96	5.80		Lyrica	PF
4323M	Capsule 150 mg	56	5	..	124.24	5.80		Lyrica	PF
4324N	Capsule 300 mg	56	5	..	183.14	5.80		Lyrica	PF

Psycholeptics

Anxiolytics

Benzodiazepine derivatives

BROMAZEPAM
Authority required
Patients with terminal disease;

Patients with refractory phobic or anxiety states.

Note
For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4150K	Tablet 3 mg	60	..	..	*29.48	5.80		Lexotan	RO
4151L	Tablet 6 mg	60	..	..	*36.10	5.80		Lexotan	RO

Azaspirodecanedione derivatives

BUSPIRONE HYDROCHLORIDE
Authority required
For the short-term treatment of anxiety.

4144D	Tablet 5 mg	50	..	..	37.99	5.80		Buspar	QA
4145E	Tablet 10 mg	50	..	..	54.84	5.80		Buspar	QA

Hypnotics and sedatives

Benzodiazepine derivatives

FLUNITRAZEPAM
Authority required
Patients with terminal disease;

Patients with refractory phobic or anxiety states.

Note
For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4216X	Tablet 1 mg	30	..	..	13.73	5.80		Hypnodorm	AF

Benzodiazepine related drugs

ZOPICLONE
Restricted benefit
For the short-term treatment of insomnia.

4522B	Tablet 7.5 mg	30	..	..	21.76	5.80	a	Imrest	AF
				..	24.92	5.80	a	Imovane	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
Other nervous system drugs								
Drugs used in addictive disorders								
Drugs used in nicotine dependence								
	NICOTINE							
	Authority required							
	Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program.							
	Note							
	Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.							
4571N	Transdermal patches releasing approximately 7 mg per 24 hours, 7	2	..	..	*51.38	5.80	QuitX	AF
4572P	Transdermal patches releasing approximately 14 mg per 24 hours, 7	2	..	..	*54.56	5.80	QuitX	AF
				..	*68.74	5.80	Nicabate CQ 14	GC
4573Q	Transdermal patches releasing approximately 21 mg per 24 hours, 7	2	2	..	*57.68	5.80	QuitX	AF
				..	*68.74	5.80	Nicabate CQ 21	GC
4576W	Transdermal patches releasing approximately 5 mg per 16 hours, 7	2	..	..	*50.82	5.80	Nicorette Patch	JT
4577X	Transdermal patches releasing approximately 10 mg per 16 hours, 7	2	..	..	*54.78	5.80	Nicorette Patch	JT
4578Y	Transdermal patches releasing approximately 15 mg per 16 hours, 7	2	2	..	*59.96	5.80	Nicorette Patch	JT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Antiparasitic products, insecticides and repellents

Anthelmintics

Antinematodal agents

Benzimidazole derivatives

MEBENDAZOLE

4325P	Tablet 100 mg	6	..	..	14.92	5.80	Vermox	BI

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Respiratory system

Nasal preparations

Decongestants and other nasal preparations for topical use

Sympathomimetics, plain

OXYMETAZOLINE HYDROCHLORIDE

4378K	Nasal spray 500 micrograms per mL (0.05%), 15 mL	‡1	..	..	17.15	5.80	Drixine	MK
4379L	Nasal spray 500 micrograms per mL (0.05%), 18 mL	‡1	..	..	16.76	5.80	Logicin Rapid Relief	QA

Antiallergic agents, excl. corticosteroids

LEVOCABASTINE HYDROCHLORIDE

4311X	Nasal spray 500 micrograms per mL (0.05%), 10 mL (100 doses)	‡1	2	..	18.24	5.80	Livostin	JT

SODIUM CROMOGLYCATE

4468E	Nasal spray metered dose pump 20 mg per mL (2%), 26 mL	‡1	5	..	22.91	5.80	Rynacrom	SW

Corticosteroids

BUDESONIDE
Restricted benefit
Severe intractable rhinitis.

4092J	Aqueous nasal spray (pump pack) 64 micrograms per dose (120 doses)	‡1	..	..	31.73	5.80	Budamax Aqueous	PM

Other nasal preparations

IPRATROPIUM BROMIDE
Restricted benefit
Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids.

4089F	Aqueous nasal spray (pump pack) 21 micrograms (anhydrous) per dose (180 doses)	‡1	5	..	23.59	5.80	Atrovent Nasal Aqueous	BY
4090G	Aqueous nasal spray (pump pack) 42 micrograms (anhydrous) per dose (180 doses)	‡1	5	..	30.47	5.80	Atrovent Nasal Forte	BY

Nasal decongestants for systemic use

Sympathomimetics

PSEUDOEPHEDRINE HYDROCHLORIDE

4029C	Tablet 60 mg	12	..	..	11.02	5.80	Logicin Sinus	QA

Cough and cold preparations

Expectorants, excl. combinations with cough suppressants

Expectorants

SENEGA and AMMONIA

4074K	Mixture 200 mL	‡1	4	..	9.18	5.80	Gold Cross	BI

Respiratory system

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
Cough suppressants, excl. combinations with expectorants									
Opium alkaloids and derivatives									
	PHOLCODINE								
4071G	Linctus 1 mg per mL (0.1%), 100 mL	‡1	2	..	9.02	5.80		Gold Cross	BI
				..	14.61	5.80		Duro-Tuss	IA
Antihistamines for systemic use									
Antihistamines for systemic use									
Piperazine derivatives									
	CETIRIZINE HYDROCHLORIDE								
4175R	Tablet 10 mg	30	..	..	29.65	5.80	a	Alzene	AF
				..	32.87	5.80		Zilarex	SZ
				..	39.45	5.80	a	Zyrtec	JT
Other antihistamines for systemic use									
	FEXOFENADINE HYDROCHLORIDE								
4237B	Tablet 60 mg	60	..	..	*54.99	5.80		Telfast	SW
4238C	Tablet 120 mg	30	..	..	29.42	5.80	a	Xergic	AF
				..	34.71	5.80	a	Fexal	SZ
				..	47.13	5.80	a	Telfast 120	SW
	LORATADINE								
4313B	Tablet 10 mg	30	..	..	32.99	5.80	a	Allereze	AF
				..	43.65	5.80	a	Lorano	SZ
				..	45.92	5.80	a	Claratyne	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Sensory organs

Ophthalmologicals

Decongestants and antiallergics

Sympathomimetics used as decongestants

ANTAZOLINE with NAPHAZOLINE

4032F	Eye drops 5 mg (phosphate)-500 micrograms (hydrochloride) per mL (0.5%-0.05%), 15 mL	‡1	1	..	14.80	5.80	Albalon-A	AG

NAPHAZOLINE HYDROCHLORIDE

4035J	Eye drops 1 mg per mL (0.1%), 15 mL	‡1	1	..	15.09	5.80	Albalon Liquifilm	AG

Other antiallergics

LEVOCABASTINE HYDROCHLORIDE

4310W	Eye drops 500 micrograms per mL (0.05%), 4 mL (120 doses)	‡1	1	..	18.24	5.80	Livostin	JT

Otologicals

Other otologicals

Indifferent preparations

CARBAMIDE PEROXIDE

4176T	Ear drops 65 mg per mL (6.5%), 12 mL	‡1	..	..	16.08	5.80	Ear Clear for Ear Wax Removal	KY

DICHLOROBENZENE with CHLORBUTOL and TURPENTINE OIL

4180B	Ear drops 20 mg-50 mg-0.1 mL per mL (2%-5%-10%), 10 mL	‡1	..	..	14.08	5.80	Cerumol	AC

DOCUSATE SODIUM

4199B	Ear drops 5 mg per mL (0.5%), 10 mL	‡1	..	..	14.47	5.80	Waxsol	NE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

Various

All other therapeutic products

All other therapeutic products

Drugs for treatment of hyperkalemia and hyperphosphatemia

	SODIUM POLYSTYRENE SULFONATE							
4470G	Oral powder 454 g	‡1	2	..	71.12	5.80	Resonium-A	SW

REPATRIATION PHARMACEUTICAL BENEFITS SCHEME (RPBS)
WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

DRESSINGS

PINK EPITHELIALISING WOUND

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	• Film; • Film Island	• Gauze—Paraffin; • Non-adherent
(B) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate)	• Hydrocolloid (Superficial Wound—Light Exudate)

RED GRANULATING WOUND

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	• Alginate (Superficial Wound);	• Alginate (Cavity Wound);

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer
	• Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)					• Foam—Moderate Exudate (see "cavity conforming" product); • Hydroactive (Cavity Wound); • Hydrocolloid (Cavity Wound)	
(B) Moisture donating	NOT APPROPRIATE						
YELLOW SLOUGHY WOUND							
Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.							
LIGHT EXUDATE:	Superficial					Cavity	
(A) Absorbing	• Cadexomer Iodine; • Foam—Light Exudate; • Foam with Charcoal; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate Exudate)					• Cadexomer Iodine; • Hydrocolloid (Cavity Wound)	
(B) Moisture Donating	• Hydrogel—Amorphous; • Hydrogel—Sheet					• Hydrogel—Amorphous	
HIGH EXUDATE:	Superficial					Cavity	
(A) Absorbing	• Alginate (Superficial Wound); • Cadexomer Iodine; • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate/High Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)					• Alginate (Cavity Wound); • Cadexomer Iodine; • Hydrocolloid (Cavity Wound)	
(B) Moisture donating	NOT APPROPRIATE						
BLACK NECROTIC WOUND							
Aim: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)							
DRY / LIGHT EXUDATE:	Superficial					Cavity	
(A) Absorbing	• Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light/Moderate					• Hydrocolloid (Cavity Wound)	

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Exudate)							
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet						• Hydrogel—Amorphous; • Hydrogel—Sheet	

INFECTED WOUNDS

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

MALODOROUS WOUNDS

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria **in** slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

MINOR SKIN TRAUMA

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

ORDERING HARTMANN PRODUCTS

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

ORDERING COLOPLAST PRODUCTS

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

ORDERING MOLNLYCKE HEALTHCARE PRODUCTS

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

All other non-therapeutic products

All other non-therapeutic products

	LUBRICATING GEL							
4306P	Tube 100 g	1	..	..	12.64	5.80	Lubri-Gel	PP

Other non-therapeutic auxiliary products

	BANDAGE—ABSORBENT WOOL							
4653X	Bandage 10 cm x 3 m	6	..	..	20.32	5.80	Surepress 650948	CC
	BANDAGE—CALICO							
4717G	Bandage, triangular, large	‡1	..	..	13.49	5.80	Handy 36361414	BV

BANDAGE—COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
4654Y	Bandage, short stretch, 8 cm x 2.6 m	5	..	..	*77.77	5.80	Comprilan 01027-00	BV
4656C	Bandage, high stretch, 7.5 cm x 3.5 m	5	..	..	*68.37	5.80	Setopress 3504	SS
4657D	Bandage, high stretch, 10 cm x 3.5 m	5	..	..	*78.57	5.80	Setopress 3505	SS
4736G	Bandage, high stretch, 7.5 cm x 3 m	5	..	..	*94.32	5.80	Tensopress 71723-01	BV
4748X	Bandage, high stretch, 10 cm x 3 m	5	..	..	*72.92	5.80	Surepress 650947	CC
				..	*126.62	5.80	Tensopress 71723-00	BV

BANDAGE—COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4598B	Bandage, four layer	5	..	..	*152.62	5.80	Profore Lite 66050415	SN
4658E	Bandage, four layer	5	..	..	*224.42	5.80	Profore 66050016	SN

BANDAGE—COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Restricted benefit

Initial treatment of venous ulcers.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4938X	Bandage, two layer, 18 cm-22 cm (red)	1	..	..	50.92	5.80	ProGuide 66000780	SN
4939Y	Bandage, two layer, 22 cm-28 cm (yellow)	1	..	..	50.92	5.80	ProGuide 66000781	SN
4940B	Bandage, two layer, 28 cm-32 cm (green)	1	..	..	50.92	5.80	ProGuide 66000782	SN

BANDAGE—COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Restricted benefit

Initial treatment of venous ulcers.

Restricted benefit

Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated.

Note

Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

4050E	Bandage, two layer	1	..	..	42.68	5.80	Coban 2	MM

BANDAGE—COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Restricted benefit

Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated.

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note							
	Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4941C	Bandage, two layer, 18 cm-22 cm (red)	4	..	..	*182.42	5.80	ProGuide 66000780	SN
4942D	Bandage, two layer, 22 cm-28 cm (yellow)	4	..	..	*182.42	5.80	ProGuide 66000781	SN
4943E	Bandage, two layer, 28 cm-32 cm (green)	4	..	..	*182.42	5.80	ProGuide 66000782	SN
	BANDAGE—RETENTION—COHESIVE—HEAVY							
4660G	Bandage 10 cm x 2 m	2	..	..	*19.36	5.80	Coban 1584	MM
4811F	Bandage 5 cm x 1.3 m	2	..	..	*14.02	5.80	Peg 7420	BK
4812G	Bandage 7.5 cm x 1.3 m	2	..	..	*17.30	5.80	Peg 7422	BK
4813H	Bandage 10 cm x 1.3 m	2	..	..	*21.04	5.80	Peg 7423	BK
4814J	Bandage 15 cm x 1.3 m	2	..	..	*28.18	5.80	Peg 7425	BK
	BANDAGE—RETENTION—COHESIVE—LIGHT							
4662J	Bandage 10 cm x 4 m	2	..	..	*17.14	5.80	Handygauze Cohesive 8635	BV
4718H	Bandages 2.5 cm x 4 m, 2	‡1	..	..	12.52	5.80	Handygauze Cohesive 8631	BV
4719J	Bandage 6 cm x 4 m	2	..	..	*14.70	5.80	Handygauze Cohesive 8633	BV
	BANDAGE—RETENTION—COTTON CREPE							
4727T	Bandage 5 cm x 2.3 m	2	..	..	*17.44	5.80	Telfa 8252F	KE
				..	*18.28	5.80	Tensocrepe 36300501	BV
4728W	Bandage 7.5 cm x 2.3 m	2	..	..	*22.22	5.80	Telfa 8253F	KE
				..	*22.40	5.80	Tensocrepe 36307501	BV
4729X	Bandage 10 cm x 2.3 m	2	..	..	*25.38	5.80	Telfa 8254F	KE
				..	*27.82	5.80	Tensocrepe 36301001	BV
	BANDAGE—TUBULAR							
4663K	Bandage, straight, size C	‡1	..	..	15.38	5.80	Elastoplast 2225	BE
4664L	Bandage, straight, size D	‡1	..	..	15.38	5.80	Elastoplast 2226	BE
4665M	Bandage, straight, size E	‡1	..	..	15.38	5.80	Elastoplast 2227	BE
4855M	Bandage 6.25 cm x 1 m	‡1	..	..	18.17	5.80	Tubigrip B 1520	SS
4856N	Bandage 6.75 cm x 1 m	‡1	..	..	18.17	5.80	Tubigrip C 1545	SS
4857P	Bandage 7.5 cm x 1 m	‡1	..	..	18.17	5.80	Tubigrip D 1546	SS
4858Q	Bandage 8.75 cm x 1 m	‡1	..	..	18.17	5.80	Tubigrip E 1547	SS
4859R	Bandage 10 cm x 1 m	‡1	..	..	18.17	5.80	Tubigrip F 1548	SS
	BANDAGE—TUBULAR (FINGER)							
4726R	Refill	‡1	..	..	13.73	5.80	Tubegauz 0501658	SS
4798M	Complete pack including applicator	‡1	..	..	17.77	5.80	Tubegauz 0501633	SS
	BANDAGE—TUBULAR (LIGHTWEIGHT)							
4671W	Bandage, small limb size (red), 10 m	‡1	..	..	28.36	5.80	Tubifast 2434	SS
4672X	Bandage, medium limb size (green), 10 m	‡1	..	..	32.02	5.80	Tubifast 2436	SS
4673Y	Bandage, large limb size (blue), 10 m	‡1	..	..	35.58	5.80	Tubifast 2438	SS

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	BANDAGE—TUBULAR (LONG STOCKING)							
4674B	Bandage, small size	2	..	..	*40.18	5.80	Tubigrip 1482	SS
4675C	Bandage, XX/large size	2	..	..	*40.18	5.80	Tubigrip 1486	SS
4797L	Bandage, medium size	2	..	..	*40.18	5.80	Tubigrip 1483	SS
4799N	Bandage, large size	2	..	..	*40.18	5.80	Tubigrip 1484	SS
	BANDAGE—TUBULAR (SHORT STOCKING)							
4661H	Bandage, small B/C size	2	..	..	*30.44	5.80	Tubigrip 1479	SS
4815K	Bandage, medium C/D size	2	..	..	*30.44	5.80	Tubigrip 1480	SS
4816L	Bandage, large D/E size	2	..	..	*30.44	5.80	Tubigrip 1481	SS
	BANDAGE—ZINC PASTE							
	Note							
	Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.							
4668Q	Bandage 7.5 cm x 6 m	2	..	..	*29.20	5.80	Zincaband 3604	SS
4669R	Bandage 7.5 cm x 6 m	2	3	..	*29.66	5.80	Steripaste 3610	XP
4670T	Bandage 10 cm x 9.1 m	2	3	..	*28.78	5.80	Flexidress 650941	CC
	BANDAGE—ZINC PASTE							
	Note							
	Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.							
	Note							
	Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4750B	Bandage 7.5 cm x 6 m	2	3	..	*73.86	5.80	Viscopaste 4948	SN
4760M	Bandages 80 cm (stockings), 4	‡1	3	..	85.17	5.80	ZipZoc 66051550	SN
	COTTON WOOL ROLL							
4701K	Roll 100 g	‡1	2	..	10.51	5.80	JJ 02013	JJ
	DRESSING—ACTIVATED CHARCOAL (MALODOROUS WOUND)							
4681J	Dressing 10.5 cm x 10.5 cm	10	..	..	*100.92	5.80	Actisorb Plus MAC031	JJ
4742N	Dressings 10 cm x 10 cm, 10	‡1	..	..	78.98	5.80	CarboFLEX 403202	CC
4743P	Dressings 15 cm x 20 cm, 5	‡1	..	..	89.87	5.80	CarboFLEX 403204	CC
	DRESSING—ALGINATE (CAVITY WOUND)							
	Note							
	This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.							
4832H	Rope 2 g	10	..	..	*109.12	5.80	Sorbsan 1411	UM
				..	*115.26	5.80	Kaltostat 168117	CC
	DRESSING—ALGINATE (CAVITY WOUND)							
	Note							
	This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.							
	Note							
	Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
4682K	Ropes 2 g (40 cm), 6	2	..	..	*137.72	5.80	Comfeel SeaSorb Filler 3740	CT

DRESSING—ALGINATE (SUPERFICIAL WOUND)

Note

This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

4684M	Dressing 5 cm x 5 cm	10	1	..	*46.92	5.80	Comfeel SeaSorb Dressing 3705	CT
4831G	Dressing 10 cm x 10 cm	10	1	..	*84.42	5.80	Sorbsan 1410	UM
				..	*90.12	5.80	Comfeel SeaSorb Dressing 3710	CT

DRESSING—ALGINATE (SUPERFICIAL WOUND)

Note

This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

4683L	Dressings 7.5 cm x 12 cm, 10	‡1	1	..	91.08	5.80	Kaltostat 168212	CC

DRESSING—ALGINATE (SUPERFICIAL WOUND)

Note

This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4691X	Dressings 15 cm x 20 cm, 10	‡1	1	..	236.07	5.80	Algisite M 66000521	SN
4699H	Dressings 5 cm x 5 cm, 10	‡1	1	..	49.40	5.80	Kaltostat 168210	CC
				..	51.28	5.80	Algisite M 66000519	SN
4700J	Dressings 10 cm x 10 cm, 10	‡1	1	..	98.42	5.80	Algisite M 66000520	SN

DRESSING—FILM

4686P	Dressings 6 cm x 7 cm, 8	‡1	..	..	15.64	5.80	Nexcare Tegaderm Transparent H1624	MM
4687Q	Dressings 10 cm x 12 cm, 4	‡1	..	..	19.65	5.80	Nexcare Tegaderm Transparent H1626	MM
4688R	Dressing 15 cm x 20 cm	6	..	..	*30.66	5.80	Tegaderm Transparent 1628	MM

DRESSING—FILM

Note

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4893M	Dressings 10 cm x 12 cm, 10	‡1	..	..	32.49	5.80	Op-Site Flexigrid 4629	SN

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	DRESSING—FILM ISLAND							
4689T	Dressing 5 cm x 7 cm	10	..	..	*16.22	5.80	Tegaderm Transparent Island 3582	MM
4690W	Dressing 9 cm x 10 cm	10	..	..	*27.72	5.80	Tegaderm Transparent Island 3586	MM

DRESSING—FILM ISLAND

Note

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4898T	Dressings 5 cm x 7.2 cm, 5	2	..	..	*28.92	5.80	Cutifilm Plus 36361370	SN
4899W	Dressings 8 cm x 10 cm, 5	2	..	..	*45.50	5.80	Cutifilm Plus 36361371	SN

DRESSING—FOAM—HEAVY EXUDATE

Note

This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4795J	Dressings 10 cm x 10 cm, 10	‡1	1	..	75.06	5.80	Lyofoam Extra 603088	XP
				..	126.67	5.80	Allevyn 66007637	SN

DRESSING—FOAM—HEAVY EXUDATE

Note

This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

4880W	Dressings 20 cm x 15 cm, 10	‡1	1	..	189.11	5.80	Lyofoam Extra 603090	XP

DRESSING—FOAM—MODERATE EXUDATE

Note

This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4590N	Dressings 12.5 cm x 12.5 cm, 10	‡1	..	..	123.23	5.80	Allevyn Adhesive 66000044	SN
4694C	Dressing, cavity, conforming, 20 g	1	1	..	88.73	5.80	Cavicare 4563	SN

DRESSING—FOAM—MODERATE EXUDATE

Note

This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

4878R	Dressings 20 cm x 15 cm, 10	‡1	1	..	101.86	5.80	Lyofoam Flat 603095	XP

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
4890J	Dressings 7.5 cm x 7.5 cm, 10	‡1	1	..	42.84	5.80	Lyofoam Flat 603092	XP
4891K	Dressings 10 cm x 10 cm, 10	‡1	1	..	49.48	5.80	Lyofoam Flat 603093	XP

DRESSING—FOAM—SILVER

Authority required

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.

Note

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4252T	Dressings, adhesive, 7.5 cm x 7.5 cm, 10	‡1	..	..	134.89	5.80	Allevyn Ag Adhesive 66800073	SN
4255Y	Dressings, adhesive, 10 cm x 10 cm, 10	‡1	..	..	200.58	5.80	Allevyn Ag Adhesive 66800075	SN
4258D	Dressings, adhesive, 12.5 cm x 12.5 cm, 10	‡1	..	..	245.05	5.80	Allevyn Ag Adhesive 66800078	SN
4259E	Dressings, non-adhesive, 10 cm x 10 cm, 10	‡1	..	..	204.42	5.80	Allevyn Ag Non-Adhesive 66800086	SN
4263J	Dressings 7.5 cm x 7.5 cm, 10	‡1	..	..	134.89	5.80	Allevyn Ag Gentle 66800460	SN
4266M	Dressings 10 cm x 10 cm, 10	‡1	..	..	200.58	5.80	Allevyn Ag Gentle 66800461	SN
4270R	Dressings 12.5 cm x 12.5 cm, 10	‡1	..	..	245.05	5.80	Allevyn Ag Gentle 66800462	SN

DRESSING—FOAM with CHARCOAL (MALODOROUS WOUND)

Note

This dressing should remain in place on wounds with odour until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

4892L	Dressings 10 cm x 10 cm, 10	2	..	..	*174.06	5.80	Lyofoam C 603025	SS

DRESSING—FOAM with SILICONE—HEAVY EXUDATE

Note

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

4642H	Dressings 7.5 cm x 7.5 cm, 5	‡1	..	..	30.77	5.80	Mepilex Border 295200	MH
4643J	Dressings 10 cm x 10 cm, 5	‡1	..	..	42.68	5.80	Mepilex Border 295300	MH

DRESSING—FOAM with SILICONE—HEAVY EXUDATE

Note

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4196W	Dressings 10 cm x 10 cm, 10	‡1	..	..	72.81	5.80	Allevyn Gentle 66800248	SN
4207K	Dressings 7.5 cm x 7.5 cm, 10	‡1	..	..	51.15	5.80	Allevyn Gentle Border 66800269	SN
4230P	Dressings 10 cm x 10 cm, 10	‡1	..	..	72.81	5.80	Allevyn Gentle Border 66800270	SN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	DRESSING—FOAM with SILICONE—LIGHT EXUDATE							
	Note							
	Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.							
4644K	Dressings 6 cm x 8.5 cm, 5	‡1	..	..	28.06	5.80	Mepilex Lite 284000	MH
4645L	Dressings 10 cm x 10 cm, 5	‡1	..	..	38.21	5.80	Mepilex Lite 284100	MH
	DRESSING—FOAM with SILICONE—MODERATE EXUDATE							
	Note							
	Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.							
4626L	Dressings 10 cm x 10 cm, 5	‡1	..	..	42.68	5.80	Mepilex 294100	MH
	DRESSING—GAUZE (ABSORBENT PAD)							
4707R	Pads 5 cm x 5 cm, 100	‡1	..	..	13.88	5.80	Handy 71117-05	BV
4708T	Pads 10 cm x 10 cm, 100	‡1	..	..	27.40	5.80	Handy 71117-06	BV
	DRESSING—GAUZE—EYE PAD							
4768Y	Pads, 12	‡1	..	..	12.83	5.80	Curity 4112	KE
	DRESSING—GAUZE—PARAFFIN							
	Note							
	Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4759L	Dressings 10 cm x 10 cm, 10	‡1	..	..	19.93	5.80	Jelonet 7404	SN
	DRESSING—GAUZE—PARAFFIN with CHLORHEXIDINE ACETATE							
	Note							
	Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4845B	Dressings 10 cm x 10 cm, 10	‡1	2	..	27.03	5.80	Bactigras 7457	SN
	DRESSING—HYDROACTIVE (CAVITY WOUND)							
	Note							
	Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4918W	Dressings 5 cm x 6 cm, 10	‡1	1	..	88.50	5.80	Allevyn Plus Cavity 66047571	SN
4919X	Dressings 10 cm x 10 cm, 5	2	1	..	*186.94	5.80	Allevyn Plus Cavity 66047573	SN
	DRESSING—HYDROACTIVE (DEBRIDEMENT)							
	Note							
	Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.							
4948K	Dressings 5.5 cm, 8	‡1	..	..	68.66	5.80	TenderWet Active Cavity	HR
4949L	Dressings 4 cm, 8	‡1	..	..	67.90	5.80	TenderWet 24	HR

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
4950M	Dressings 7.5 cm x 7.5 cm, 8	‡1	..	..	92.19	5.80	Active TenderWet 24 Active	HR
	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—HIGH EXUDATE)							
4692Y	Dressings (foam alternative) 10 cm x 10 cm, 10	‡1	..	..	54.90	5.80	CombiDERM 651031	CC
4693B	Dressings (foam alternative) 15 cm x 18 cm, 5	‡1	..	..	71.72	5.80	CombiDERM 651027	CC
4695D	Dressings, island, 11 cm x 11 cm, 10	‡1	..	..	111.24	5.80	Tielle MTL101E	JJ
4696E	Dressings, island, 18 cm x 18 cm, 5	‡1	..	..	135.84	5.80	Tielle MT2442	JJ

DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—HIGH EXUDATE)

Note

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

4927H	Non-adhesive waterproof semi-permeable absorbent foam pads 10 cm x 10 cm, 10	‡1	1	..	87.93	5.80	Biatain Non-adhesive 3410	CT
4928J	Non-adhesive waterproof semi-permeable absorbent foam pads 15 cm x 15 cm, 5	‡1	2	..	86.45	5.80	Biatain Non-adhesive 3413	CT
4929K	Adhesive waterproof semi-permeable absorbent foam pads 12 cm x 12 cm, 10	‡1	1	..	96.95	5.80	Biatain Adhesive 3420	CT
4930L	Adhesive waterproof semi-permeable absorbent foam pads 18 cm x 18 cm, 5	‡1	2	..	93.82	5.80	Biatain Adhesive 3423	CT

DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—LIGHT EXUDATE)

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4905E	Dressings 5 cm x 6 cm, 10	‡1	1	..	59.19	5.80	Allevyn Thin 66047576	SN
4906F	Dressings 10 cm x 10 cm, 5	2	1	..	*108.32	5.80	Allevyn Thin 66047578	SN

DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—MODERATE EXUDATE)

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4885D	Dressings 5 cm x 6 cm, 10	‡1	1	..	47.89	5.80	Cutinova Hydro 66047441	SN
4886E	Dressings 10 cm x 10 cm, 5	2	1	..	*79.44	5.80	Cutinova Hydro 66047443	SN

DRESSING—HYDROCOLLOID (CAVITY WOUND)

Note

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

4896Q	Paste 30 g	10	..	..	*145.12	5.80	DuoDERM Paste H7930	CC

DRESSING—HYDROCOLLOID (CAVITY WOUND)

Note

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.							
4895P	Paste 50 g	2	3	..	*43.22	5.80	Comfeel Paste 4701	CT
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—LIGHT EXUDATE) **Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.							
	Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.							
4888G	Dressings 5 cm x 7 cm, 10	‡1	1	..	41.72	5.80	Comfeel Plus Transparent 3530	CT
4889H	Dressings 9 cm x 14 cm, 10	‡1	1	..	84.52	5.80	Comfeel Plus Transparent 3536	CT
4924E	Dressings 10 cm x 10 cm, 10	‡1	1	..	69.78	5.80	Comfeel Plus Transparent 3533	CT
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—LIGHT EXUDATE) **Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.							
4907G	Dressings 10 cm x 10 cm, 10	‡1	1	..	71.72	5.80	DuoDERM Extra Thin H7955	CC
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—LIGHT EXUDATE) **Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.							
	Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.							
4947J	Dressings 10 cm x 10 cm, 10	‡1	1	..	48.15	5.80	Hydrocoll Thin 900758	HR
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—MODERATE EXUDATE) **Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.							
4897R	Dressings 10 cm x 10 cm, 5	2	1	..	*81.40	5.80	DuoDERM CGF H7660	CC
4920Y	Dressings 20 cm x 20 cm, 5	2	1	..	*222.32	5.80	DuoDERM CGF H7662	CC
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—MODERATE EXUDATE) **Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4921B	Dressings 10 cm x 10 cm, 10	‡1	1	..	80.30	5.80	Replicare Ultra 66000434	SN
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—MODERATE EXUDATE)							
	Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.							
	Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.							
4945G	Dressings 10 cm x 10 cm, 10	‡1	1	..	48.15	5.80	Hydrocoll 900744	HR
4946H	Dressings 15 cm x 15 cm, 10	‡1	1	..	89.91	5.80	Hydrocoll 900936	HR
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—MODERATE EXUDATE)							
	Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.							
	Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.							
4678F	Butterfly shape 7 cm	5	..	..	*55.17	5.80	Comfeel Plus Pressure Relieving 3350	CT
4679G	Round 10 cm	5	..	..	*59.62	5.80	Comfeel Plus Pressure Relieving 3353	CT
4923D	Dressings with alginate 10 cm x 10 cm, 10	‡1	1	..	81.99	5.80	Comfeel Plus Ulcer Dressing 3110	CT
	DRESSING—HYDROFIBRE (ALTERNATE TO ALGINATES)							
4649Q	Dressings 10 cm x 10 cm, 10	‡1	1	..	100.98	5.80	Aquacel 177902	CC
4698G	Ropes 2 g (30 cm), 5	‡1	1	..	83.71	5.80	Aquacel 177904	CC
4922C	Dressings 15 cm x 15 cm, 5	2	1	..	*208.70	5.80	Aquacel 177903	CC
	DRESSING—HYDROGEL—AMORPHOUS							
	Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.							
	Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.							
4912M	Tubes 15 g, 10	‡1	1	..	64.48	5.80	DuoDERM Gel H7990	CC
				..	72.09	5.80	Comfeel Purilon Gel 3900	CT
	DRESSING—HYDROGEL—AMORPHOUS							
	Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.							

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
4913N	Tubes 30 g, 3	3	1	..	*97.11	5.80	DuoDERM Gel H7987	CC
4914P	Tube 50 g	3	3	..	*33.12	5.80	Solugel 10336	JJ

DRESSING—HYDROGEL—AMORPHOUS

Note

This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4599C	Tube 50 g	3	3	..	*30.51	5.80	SoloSite Gel 36361338	SN
4894N	Tube 25 g	4	3	..	*62.18	5.80	Intrasite Gel 7313	SN

DRESSING—HYDROGEL—SHEET

Note

This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

4911L	Dressings 9.5 cm x 10.2 cm, 5	2	..	..	*83.20	5.80	Nu-Gel 2497	JJ

DRESSING—HYDROGEL—SHEET

Note

This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

Note

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

4806Y	Dressings 10 cm x 10 cm, 5	2	..	..	*53.28	5.80	Aquaclear 900796	HR

DRESSING—NON-ADHERENT

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4819P	Dressings 5 cm x 5 cm, 5	2	..	..	*15.80	5.80	Cutilin Non-Stick Wound Pad 36361374	SN
4860T	Dressings 5 cm x 5 cm, 5	2	..	..	*16.48	5.80	Melolin 36361357	SN
4861W	Dressings 10 cm x 10 cm, 10	‡1	..	..	33.70	5.80	Melolin 66974933	SN
4862X	Dressings 10 cm x 10 cm, 5	2	..	..	*25.40	5.80	Cutilin Non-Stick Wound Pad 36361375	SN

DRESSING—NON-ADHERENT

4755G	Dressings 5 cm x 7.5 cm, 10	‡1	..	..	11.02	5.80	Telfa 1970C	KE
4758K	Dressings 7.5 cm x 10 cm, 6	‡1	..	..	11.23	5.80	Telfa 2140C	KE
4844Y	Dressings, self-adhesive, 7.5 cm x 10 cm, 6	‡1	2	..	12.02	5.80	Telfa 7650C	KE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	DRESSING—NON-ADHERENT							
	Note							
	Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.							
4944F	Dressings 7.5 cm x 10 cm, 10	‡1	..	..	15.24	5.80	Atrauman 499513	HR
	DRESSING—NON-ADHERENT							
	Note							
	Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.							
4243H	Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10	‡1	..	..	63.62	5.80	Mepitel 290510	MH
4244J	Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10	‡1	..	..	107.62	5.80	Mepitel 290710	MH
	DRESSING—TULLE NON-GAUZE—PARAFFIN							
4909J	Dressing 7.6 cm x 7.6 cm	10	1	..	*15.72	5.80	Adaptic 2012	JJ
	DRESSING with CADEXOMER IODINE							
	Note							
	Suitable for yellow sloughy infected and malodorous wounds.							
	Note							
	Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4931M	Sachets 3 g, 7	‡1	2	..	67.37	5.80	Iodosorb Powder 66051070	SN
4932N	Tubes 10 g, 4	‡1	2	..	108.57	5.80	Iodosorb Ointment 66051240	SN
4933P	Tubes 20 g, 2	‡1	2	..	107.55	5.80	Iodosorb Ointment 66051230	SN
4935R	Sheets 5 g (6 cm x 4 cm), 5	‡1	2	..	102.62	5.80	Iodosorb 66051330	SN
4936T	Sachets 10 g (8 cm x 6 cm), 3	‡1	2	..	148.35	5.80	Iodosorb 66051340	SN
4937W	Sheets 17 g (10 cm x 8 cm), 2	‡1	..	..	156.36	5.80	Iodosorb 66051360	SN
	DRESSING with SILVER							
	Authority required							
	For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.							
	Note							
	Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.							
4646M	Hydroactive dressings non-adhesive 10 cm x 10 cm, 5	‡1	..	..	175.89	5.80	Biatain Ag 9622	CT
4647N	Hydroactive dressings adhesive 12.5 cm x 12.5 cm, 5	‡1	..	..	191.29	5.80	Biatain Ag 9632	CT
	DRESSING with SILVER							
	Authority required							
	For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.							
	Note							
	Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.							

Various

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
4648P	Tulle dressings 10 cm x 10 cm, 3	‡1	..	..	43.78	5.80	Atrauman Ag 499572	HR
	GAUZE and COTTON TISSUE (COMBINE ROLL)							
4761N	Wrapped pack 10 cm x 10 m	‡1	..	..	17.21	5.80	JJ 12010	JJ
4767X	Wrapped pack 9 cm x 10 m	‡1	..	..	15.39	5.80	BSN 2902165	BV
	TAPES—NON-WOVEN RETENTION (POLYACRYLATE)							
4915Q	Roll 2.5 cm x 9.1 m	‡1	..	..	12.87	5.80	Medipore 2961	MM
	TAPES—NON-WOVEN RETENTION (POLYACRYLATE)							
	Note							
	Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.							
4917T	Roll 2.5 cm x 10 m	‡1	..	..	11.04	5.80	Mefix 310250	MH
	TAPES—PLASTER ADHESIVE (WITH SILICONE)							
	Note							
	Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.							
4239D	Roll 2 cm x 3 m	‡1	..	..	21.37	5.80	Mepitac 298300	MH
4240E	Roll 4 cm x 1.5 m	‡1	..	..	21.37	5.80	Mepitac 298400	MH
	TAPES—PLASTER ADHESIVE ELASTIC							
4780N	Roll 2.5 cm x 2.5 m	‡1	..	..	12.76	5.80	Leukoplast 01071-00	BV
4781P	Roll 5 cm x 2.5 m	‡1	..	..	18.56	5.80	Leukoplast 01072-00	BV
4782Q	Roll 7.5 cm x 2.5 m	‡1	..	..	22.13	5.80	Leukoplast 01073-00	BV
	TAPES—PLASTER ADHESIVE HYPOALLERGENIC							
4783R	Roll 1.25 cm x 5 m	‡1	..	..	10.34	5.80	Leukopor 2471	BV
4785W	Roll 1.25 cm x 5 m	‡1	..	..	10.62	5.80	Leukosilk 1021	BV
4787Y	Roll 2.5 cm x 5 m	‡1	..	..	13.24	5.80	Leukosilk 1022	BV
4788B	Stretch roll 5 cm x 5 m	‡1	..	..	17.21	5.80	Leukoflex 1124	BV
4789C	Roll 5 cm x 5 m	‡1	..	..	17.05	5.80	Leukosilk 1024	BV
4790D	Roll 5 cm x 5 m	‡1	..	..	16.21	5.80	Leukopor 2474	BV
4794H	Roll 2.5 cm x 5 m	‡1	..	..	12.73	5.80	Leukopor 2472	BV
4848E	Roll (dispenser) 1.9 cm x 5.4 m	‡1	..	..	11.05	5.80	Nexcare Durable Cloth First Aid Tape 799	MM
4849F	Roll (dispenser) 1.9 cm x 7.3 m	‡1	..	..	11.05	5.80	Nexcare Gentle Paper First Aid Tape 789	MM

Section 2

Standard Packs and Prices

NOTE—

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 1 of the Schedule.

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
4579B	ALPROSTADIL	10 mcg	2@	25.40	PF
4580C		20 mcg	2@	32.40	PF
4118R	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE	400 mg-400 mg-30 mg per 5 mL, 500 mL	1@	8.11	JT
4453J		400 mg-400 mg-40 mg	100@	19.85	JT
4598B	BANDAGE—COMPRESSION	Four layer	1@	29.24	SN
4654Y		8 cm x 2.6 m	1@	14.27	BV
4656C		7.5 cm x 3.5 m	1@	12.39	SS
4657D		10 cm x 3.5 m	1@	14.43	SS
4658E		Four layer	1@	43.60	SN
4736G		7.5 cm x 3 m	1@	17.58	BV
4748X		10 cm x 3 m	1@	24.04	BV
4941C		Two layer, 18 cm-22 cm	1@	44.00	SN
4942D		Two layer, 22 cm-28 cm	1@	44.00	SN
4943E		Two layer, 28 cm-32 cm	1@	44.00	SN
4660G	BANDAGE—RETENTION—COHESIVE—HEAVY	10 cm x 2 m	1@	6.47	MM
4811F		5 cm x 1.3 m	1@	3.80	BK
4812G		7.5 cm x 1.3 m	1@	5.44	BK
4813H		10 cm x 1.3 m	1@	7.31	BK
4814J		15 cm x 1.3 m	1@	10.88	BK
4662J	BANDAGE—RETENTION—COHESIVE—LIGHT	10 cm x 4 m	1@	5.36	BV
4719J		6 cm x 4 m	1@	4.14	BV
4727T	BANDAGE—RETENTION—COTTON CREPE	5 cm x 2.3 m	1@	5.93	BV
4728W		7.5 cm x 2.3 m	1@	7.99	BV
4729X		10 cm x 2.3 m	1@	10.70	BV
4674B	BANDAGE—TUBULAR (LONG STOCKING)	Small	1@	16.88	SS
4675C		XX/large	1@	16.88	SS
4797L		Medium	1@	16.88	SS
4799N		Large	1@	16.88	SS
4661H	BANDAGE—TUBULAR (SHORT STOCKING)	Small B/C	1@	12.01	SS
4815K		Medium C/D	1@	12.01	SS
4816L		Large D/E	1@	12.01	SS
4668Q	BANDAGE—ZINC PASTE	7.5 cm x 6 m	1@	11.39	SS
4669R		7.5 cm x 6 m	1@	11.62	XP
4670T		10 cm x 9.1 m	1@	11.18	CC
4750B		7.5 cm x 6 m	1@	33.72	SN
4150K	BROMAZEPAM	3 mg	30@	11.53	RO
4151L		6 mg	30@	14.84	RO
4094L	CALCIUM	500 mg	60@	6.01	IA
4142B		600 mg	120@	7.89	PP
4333C		500 mg	60@	6.01	IA
4055K	CALCIUM CARBONATE with GLYCINE	420 mg-180 mg	100@	8.38	MM
4681J	DRESSING—ACTIVATED CHARCOAL (MALODOROUS WOUND)	10.5 cm x 10.5 cm	1@	9.45	JJ
4682K	DRESSING—ALGINATE (CAVITY WOUND)	2 g (40 cm), 6	1@	65.65	CT
4832H		2 g	5@	54.42	CC
4684M	DRESSING—ALGINATE (SUPERFICIAL WOUND)	5 cm x 5 cm	1@	4.05	CT
4831G		10 cm x 10 cm	1@	7.80	UM
4688R	DRESSING—FILM	15 cm x 20 cm	1@	4.04	MM
4689T	DRESSING—FILM ISLAND	5 cm x 7 cm	1@	0.98	MM
4690W		9 cm x 10 cm	1@	2.13	MM
4898T		5 cm x 7.2 cm, 5	1@	11.25	SN
4899W		8 cm x 10 cm, 5	1@	19.54	SN
4892L	DRESSING—FOAM with CHARCOAL (MALODOROUS WOUND)	10 cm x 10 cm, 10	1@	83.82	SS
4919X	DRESSING—HYDROACTIVE (CAVITY	10 cm x 10 cm, 5	1@	90.26	SN

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price	$	Manufacturer
	WOUND)				
4906F	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—LIGHT EXUDATE)	10 cm x 10 cm, 5	1@	50.95	SN
4886E	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—MODERATE EXUDATE)	10 cm x 10 cm, 5	1@	36.51	SN
4895P	DRESSING—HYDROCOLLOID (CAVITY WOUND)	50 g	1@	18.40	CT
4896Q		30 g	1@	13.87	CC
4678F	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—MODERATE EXUDATE)	7 cm	1@	9.75	CT
4679G		10 cm	1@	10.64	CT
4897R		10 cm x 10 cm, 5	1@	37.49	CC
4920Y		20 cm x 20 cm, 5	1@	107.95	CC
4922C	DRESSING—HYDROFIBRE (ALTERNATE TO ALGINATES)	15 cm x 15 cm, 5	1@	101.14	CC
4599C	DRESSING—HYDROGEL—AMORPHOUS	50 g	1@	8.03	SN
4894N		25 g	1@	13.94	SN
4913N		30 g, 3	1@	30.23	CC
4914P		50 g	1@	8.90	JJ
4806Y	DRESSING—HYDROGEL—SHEET	10 cm x 10 cm, 5	1@	23.43	HR
4911L		9.5 cm x 10.2 cm, 5	1@	38.39	JJ
4819P	DRESSING—NON-ADHERENT	5 cm x 5 cm, 5	1@	4.69	SN
4860T		5 cm x 5 cm, 5	1@	5.03	SN
4862X		10 cm x 10 cm, 5	1@	9.49	SN
4909J	DRESSING—TULLE NON-GAUZE—PARAFFIN	7.6 cm x 7.6 cm	1@	0.93	JJ
4237B	FEXOFENADINE HYDROCHLORIDE	60 mg	20@	16.19	SW
4246L	GLYCEROL	2.8 g, 12	1@	4.66	PP
4571N	NICOTINE	Approx. 7 mg per 24 hours, 7	1@	22.48	AF
4572P		Approx. 14 mg per 24 hours, 7	1@	31.16	GC
4573Q		Approx. 21 mg per 24 hours, 7	1@	31.16	GC
4576W		Approx. 5 mg per 16 hours, 7	1@	22.20	JT
4577X		Approx. 10 mg per 16 hours, 7	1@	24.18	JT
4578Y		Approx. 15 mg per 16 hours, 7	1@	26.77	JT

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THERAPEUTIC GROUP PREMIUM POLICY

PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A THERAPEUTIC GROUP PREMIUM WITH EFFECT FROM 1 June 2012

The Schedule of Pharmaceutical Benefits shows differences in price in some therapeutic groups where alternative drugs may have a therapeutic group premium.

The Therapeutic Group Premium Policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety and health outcomes.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group. This means that consumers may have to pay for more expensive drugs (those with a therapeutic group premium). This extra amount does not count towards their PBS safety net threshold.

Therapeutic group premiums apply where a prescriber has prescribed a drug within a therapeutic group that attracts a therapeutic group premium and has not sought an exemption from Medicare Australia on clinical grounds.

The exemption provisions are:

- adverse effects occurring with all of the base-priced drugs; or
- drug interactions occurring with all of the base-priced drugs; or
- drug interactions expected to occur with all of the base-priced drugs; or
- transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

The premiums are not a Government charge but reflect the fact that the supplier(s) of the drug charge a price higher than the Government is willing to subsidise.

Under the Therapeutic Group Premium Policy drug substitution by pharmacists is not permitted.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a therapeutic group premium.

Premium Priced Brand	Form and Strength	Max Qty	Therap eutic Group Premium $
H_2-RECEPTOR ANTAGONISTS			
Zantac	Effervescent tablet 150 mg (base)	60	3.16
Zantac Syrup	Syrup 150 mg (base) per 10 mL, 300 mL	2	2.20
The base-priced drugs in this therapeutic group are cimetidine, nizatidine and ranitidine hydrochloride (except ranitidine hydrochloride effervescent tablet 150 mg (base) and syrup 150 mg (base) per 10 mL, 300 mL).			
ANGIOTENSIN II ANTAGONISTS			
Atacand	Tablet 8 mg	30	2.95
Atacand	Tablet 16 mg	30	3.26
Atacand	Tablet 32 mg	30	2.87
Teveten	Tablet 400 mg (base)	56	3.48
Teveten	Tablet 600 mg (base)	28	2.00
Olmetec	Tablet 20 mg	30	1.00
Olmetec	Tablet 40 mg	30	1.00
Micardis	Tablet 40 mg	28	2.00
Micardis	Tablet 80 mg	28	1.99
The base-priced drugs in this therapeutic group are candesartan cilexetil (Tablet 4 mg), irbesartan, and valsartan.			

BRAND PREMIUM POLICY

BRANDS OF PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A BRAND PREMIUM AND THAT MAY BE SUBSTITUTED WITH EFFECT FROM 1 June 2012

The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product.

Manufacturers can develop generic equivalents and apply to have them listed on the PBS. In doing this, manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). This extra amount does not count towards their PBS safety net threshold.

Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

Prescription forms supplied by Medicare Australia contain a box to be ticked where brand substitution is not to take place.

Prescribers not using these prescription forms should endorse the prescription if brand substitution is not permitted. Where a stamp is used for this purpose, the prescriber will be required to initial the stamped statement.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a brand premium and that can be substituted where permitted. They are listed alphabetically, by brand name, with the brand premium and benchmark brand(s) cited in the last column.

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Abbocillin-V	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	2	1.90	*Cilicaine V*
Accupril	Tablet 5 mg (as hydrochloride)	30	0.34	*Acquin 5; Acquin Aspen 5; APO-Quinapril; Aquinafil; Pharmacor Quinapril 5; Qpril 5; Quinapril generichealth; Quinapril Pfizer; Quinapril Sandoz*
	Tablet 10 mg (as hydrochloride)	30	0.47	*Acquin 10; Acquin Aspen 10; APO-Quinapril; Aquinafil; Pharmacor Quinapril 10; Qpril 10; Quinapril generichealth; Quinapril Pfizer*
	Tablet 20 mg (as hydrochloride)	30	0.72	*Acquin 20; Acquin Aspen 20; APO-Quinapril; Aquinafil; Pharmacor Quinapril 20; Qpril 20; Quinapril-GA; Quinapril generichealth; Quinapril Pfizer; Quinapril Sandoz*
Adalat 10	Tablet 10 mg	60	0.95	*Adefin 10*
Adalat 20	Tablet 20 mg	60	1.76	*Adefin 20; GenRx Nifedipine; Nifehexal*
Adalat Oros 30	Tablet 30 mg (controlled release)	30	2.03	*Addos XR 30; Adefin XL 30; APO-Nifedipine XR*
Adalat Oros 60	Tablet 60 mg (controlled release)	30	2.24	*Addos XR 60; Adefin XL 60; APO-Nifedipine XR*
Aldactone	Tablet 25 mg	100	1.75	*Spiractin 25*
	Tablet 100 mg	100	2.40	*Spiractin 100*
Aldomet	Tablet 250 mg	100	2.50	*Hydopa*
Alphagan	Eye drops 2 mg per mL (0.2%), 5 mL	1	1.63	*Enidin*
Amaryl	Tablet 1 mg	30	2.06	*APO-Glimepiride; Aylide 1; Diapride 1; Dimirel; Glimepiride GA 1; Glimepiride Sandoz; Pharmacor Glimepiride 1*
	Tablet 2 mg	30	2.07	*APO-Glimepiride; Aylide 2; Diapride 2; Dimirel; Glimepiride GA 2; Glimepiride Sandoz; Pharmacor Glimepiride 2*
	Tablet 3 mg	30	2.04	*APO-Glimepiride; Aylide 3; Diapride 3; Dimirel; Glimepiride GA 3; Glimepiride Sandoz; Pharmacor Glimepiride 3*
	Tablet 4 mg	30	2.06	*APO-Glimepiride; Aylide 4; Diapride 4; Dimirel; Glimepiride GA 4; Glimepiride Sandoz; Pharmacor Glimepiride 4*
Amoxil	Capsule 250 mg	20	0.88	*Alphamox 250; Amoxycillin-GA; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Terry White Chemists Amoxycillin*
	Capsule 500 mg	20	0.89	*Alphamox 500; Amoxycillin-GA; Amoxycillin generichealth 500; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Terry White Chemists Amoxycillin*
	Powder for syrup 125 mg per 5 mL, 100 mL	1	0.89	*Alphamox 125; Amoxycillin Sandoz; Bgramin; Chem mart Amoxycillin; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin*
Amoxil Forte	Powder for syrup 250 mg per 5 mL, 100 mL	1	0.87	*Alphamox 250; Amoxycillin Sandoz; Bgramin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin*
Anafranil 25	Tablet 25 mg	50	3.06	*Chem mart Clomipramine; GenRx Clomipramine; Placil; Terry White Chemists Clomipramine*
Anaprox 550	Tablet 550 mg	50	2.17	*Crysanal*
Androcur	Tablet 50 mg	20	2.97	*Cyprohexal; Cyprone; Cyprostat; GenRx Cyproterone Acetate; Procur*
	Tablet 50 mg	100	3.12	*Cyprohexal; Cyprone; Cyprostat; GenRx Cyproterone Acetate; Procur*
Androcur-100	Tablet 100 mg	50	1.56	*Cyprohexal; Cyprostat-100; GenRx Cyproterone Acetate; Procur 100*
Anginine Stabilised	Tablets 600 micrograms, 100	1	2.94	*Lycinate*
Aristocort 0.02%	Cream 200 micrograms per g (0.02%), 100 g	2	3.78	*Tricortone*
	Ointment 200 micrograms per g (0.02%), 100 g	2	3.78	*Tricortone*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Aropax	Tablet 20 mg (as hydrochloride)	30	0.80	*Chem mart Paroxetine; Extine 20; GenRx Paroxetine; Paroxetine 20; Paroxetine-GA; Paroxetine Sandoz; Paxtine; Roxet 20; Terry White Chemists Paroxetine*
Astrix	Tablet 100 mg	112	1.29	*Mayne Pharma Aspirin*
Atrovent	Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30	2	0.68	*Aeron 250; APO-Ipratropium; Ipratrin; Ipravent*
Atrovent Adult	Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30	2	0.58	*Aeron 500; APO-Ipratropium; Ipratrin Adult; Ipravent*
Augmentin	Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL	1	1.58	*Clamoxyl; Curam*
Augmentin Duo	Tablet 500 mg-125 mg	10	1.57	*Amoxycillin/ Clavulanic Acid 500/125 generichealth; APO-Amoxycillin/ Clavulanic Acid 500/125; Clamoxyl Duo; Curam Duo 500/125; GA-Amclav 500/125; Moxiclav Duo 500/125*
Augmentin Duo 400	Powder for syrup 400 mg-57 mg per 5 mL, 60 mL	1	1.58	*Clamoxyl Duo 400; Curam Duo*
Augmentin Duo forte	Tablet 875 mg-125 mg	10	1.56	*Amoxycillin/ Clavulanic Acid 875/125 generichealth; Chem mart Amoxycillin and Clavulanic Acid; Clamoxyl Duo forte; Clavycillin 875/125; Curam Duo Forte 875/125; GA-Amclav Forte 875/125; GenRx Amoxycillin and Clavulanic Acid; Moxiclav Duo Forte 875/125; Terry White Chemists Amoxycillin and Clavulanic Acid*
Aurorix	Tablet 150 mg	60	0.55	*Amira 150; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Moclobemide Sandoz; Mohexal; Terry White Chemists Moclobemide*
Aurorix 300 mg	Tablet 300 mg	60	1.10	*Amira 300; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Moclobemide Sandoz; Terry White Chemists Moclobemide*
Avanza	Tablet 30 mg	30	2.60	*Aurozapine 30; Axit 30; Chem mart Mirtazapine; GenRx Mirtazapine; Mirtazapine-DP; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine*
	Tablet 45 mg	30	2.84	*APO-Mirtazapine; Aurozapine 45; Axit 45; Chem mart Mirtazapine; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine*
Azopt	Eye drops 10 mg per mL (1%), 5 mL	1	1.18	*BrinzoQuin*
Betaloc	Tablet 50 mg	100	2.51	*Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metrol 50; Minax 50; Terry White Chemists Metoprolol*
	Tablet 100 mg	60	2.50	*Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metrol 100; Minax 100; Terry White Chemists Metoprolol*
Betnovate 1/2	Cream 500 micrograms (base) per g (0.05%), 15 g	1	2.94	*Cortival 1/2*
	Ointment 500 micrograms (base) per g (0.05%), 15 g	1	2.94	*Cortival 1/2*
Betnovate 1/5	Cream 200 micrograms (base) per g (0.02%), 100 g	2	6.88	*Cortival 1/5*
Betoptic	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	1	2.09	*BetoQuin*
Brevinor	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	4	7.68	*Norimin 28 Day*
Brevinor-1	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	7.68	*Norimin-1 28 Day*
Capoten	Tablet 25 mg	90	4.03	*Captopril Sandoz; GenRx Captopril; Zedace*
	Tablet 50 mg	90	4.03	*Captopril Sandoz; GenRx Captopril; Zedace*
Carafate	Tablet equivalent to 1 g anhydrous sucralfate	120	2.06	*Ulcyte*
Ceclor	Powder for oral suspension 125 mg per 5 mL, 100 mL	1	3.16	*Aclor 125; Cefaclor Sandoz; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Ozcef; Terry White Chemists Cefaclor*
	Powder for oral suspension 250 mg per 5 mL, 75 mL	1	3.31	*Aclor 250; Cefaclor Sandoz; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Ozcef;*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Ceclor CD	Tablet 375 mg (sustained release)	10	3.93	*Terry White Chemists Cefaclor Cefaclor-GA; Cefaclor GH; Chem mart Cefaclor CD; GenRx Cefaclor CD; Karlor CD; Keflor CD; Ozcef; Terry White Chemists Cefaclor CD*
Celestone-M	Cream 200 micrograms (base) per g (0.02%), 100 g	2	2.46	*Antroquoril*
	Ointment 200 micrograms (base) per g (0.02%), 100 g	2	2.46	*Antroquoril*
Ciloxan	Eye drops 3 mg per mL (0.3%), 5 mL	2	2.06	*CiloQuin*
Cipramil	Tablet 20 mg (base)	28	2.00	*APO-Citalopram; Auro-Citalopram 20; Celapram; Celica; Chem mart Citalopram; Ciazil; Citalobell; Citalopram 20; Citalopram-GA; Citalopram generichealth; Citalopram Pfizer; Citalopram Sandoz; GenRx Citalopram; Pharmacor Citalo 20; Talam; Terry White Chemists Citalopram*
Ciproxin 250	Tablet 250 mg	14	0.79	*C-Flox 250; Cifran; Ciprofloxacin-DRLA; Ciprofloxacin Sandoz; Ciprol 250; GenRx Ciprofloxacin; Profloxin*
Ciproxin 500	Tablet 500 mg	14	0.79	*C-Flox 500; Cifran; Ciprofloxacin 500; Ciprofloxacin-BW; Ciprofloxacin-DRLA; Ciprofloxacin-GA; Ciprofloxacin-PS; Ciprofloxacin Sandoz; Ciprol 500; GenRx Ciprofloxacin*
Ciproxin 750	Tablet 750 mg	14	0.78	*C-Flox 750; Cifran; Ciprofloxacin 750; Ciprofloxacin-BW; Ciprofloxacin-DRLA; Ciprofloxacin-GA; Ciprofloxacin-PS; Ciprofloxacin Sandoz; Ciprol 750; GenRx Ciprofloxacin*
Colgout	Tablet 500 micrograms	30	0.85	*Lengout*
Dalacin C	Capsule 150 mg	24	1.37	*Cleocin*
Daonil	Tablet 5 mg	100	1.44	*Glimel*
Depo-Medrol	Injection 40 mg in 1 mL	5	0.60	*Depo-Nisolone*
Depo-Provera	Injection 150 mg in 1 mL	1	3.20	*Depo-Ralovera*
Diabex	Tablet 500 mg	100	1.41	*APO-Metformin 500; Chem mart Metformin; Diaformin; Formet 500; GenRx Metformin; Glucobete 500; Glucophage; Metformin 500; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin*
Diabex 1000	Tablet 1 g	90	1.43	*APO-Metformin 1000; Chem mart Metformin 1000; Diaformin 1000; Formet 1000; Glucobete 1000; Metformin-GA; Metformin generichealth 1000; Metformin Ranbaxy 1000; Metformin Sandoz; Pharmacor Metformin 1000; Terry White Chemists Metformin 1000*
Diabex 850	Tablet 850 mg	60	1.41	*APO-Metformin 850; Chem mart Metformin; Diaformin 850; Formet 850; GenRx Metformin; Glucobete 850; Glucophage; Metformin 850; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin*
Diprosone	Cream 500 micrograms (base) per g (0.05%), 15 g	1	2.45	*Eleuphrat*
	Ointment 500 micrograms (base) per g (0.05%), 15 g	1	2.45	*Eleuphrat*
Doryx	Capsule 100 mg (as hydrochloride)	7	1.10	*Mayne Pharma Doxycycline*
	Capsule 50 mg (as hydrochloride)	25	1.24	*Mayne Pharma Doxycycline*
	Capsule 100 mg (as hydrochloride)	28	4.40	*Mayne Pharma Doxycycline*
	Capsule 100 mg (as hydrochloride)	21	1.97	*Mayne Pharma Doxycycline*
Dulcolax	Suppositories 10 mg, 10	3	1.50	*Petrus Bisacodyl Suppositories*
Duphalac	Mixture 3.34 g per 5 mL, 500 mL	1	1.20	*Actilax; Genlac; GenRx Lactulose; Lac-Dol; Lactocur*
	Mixture 3.34 g per 5 mL, 500 mL	3	3.60	*Actilax; Genlac; GenRx Lactulose; Lac-Dol; Lactocur*
Duratears	Compound eye ointment 3.5 g	2	2.18	*Poly Visc*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
E.E.S. 200	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	1	2.71	*E-Mycin 200*
E.E.S. 400 Filmtab	Tablet 400 mg (base)	25	2.66	*E-Mycin*
E.E.S. Granules	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	1	2.73	*E-Mycin 400*
Elocon	Cream 1 mg per g (0.1%), 15 g	1	2.45	*Novasone*
	Ointment 1 mg per g (0.1%), 15 g	1	2.45	*Novasone*
	Lotion 1 mg per g (0.1% w/w), 30 mL	1	2.45	*Novasone*
Epilim EC	Tablet 200 mg (enteric coated)	200	2.00	*Sodium Valproate Sandoz; Valprease 200; Valpro 200; Valproate Winthrop EC 200*
	Tablet 500 mg (enteric coated)	200	2.00	*Sodium Valproate Sandoz; Valprease 500; Valpro 500; Valproate Winthrop EC 500*
Eryc	Capsule 250 mg	25	2.38	*Mayne Pharma Erythromycin*
Fasigyn	Tablet 500 mg	4	2.42	*Simplotan*
Feldene	Capsule 10 mg	50	2.52	*Chem mart Piroxicam; GenRx Piroxicam; Mobilis 10; Terry White Chemists Piroxicam*
	Capsule 20 mg	25	2.49	*Chem mart Piroxicam; GenRx Piroxicam; Mobilis 20; Terry White Chemists Piroxicam*
Feldene-D	Dispersible tablet 20 mg	25	2.49	*Mobilis D-20*
Flagyl	Tablet 400 mg	21	2.30	*Metrogyl 400; Metronide 400*
	Tablet 200 mg	21	2.30	*Metrogyl 200; Metronide 200*
Fosamax Once Weekly	Tablet equivalent to 70 mg alendronic acid	4	2.05	*Adronat; Alendrobell 70mg; Alendronate-GA; Alendronate Sandoz; Alendro Once Weekly; APO-Alendronate; Chem mart Alendronate 70mg; Densate 70; Ossmax 70mg; Terry White Chemists Alendronate 70mg*
Fosamax Plus 70 mg/140 mcg	Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol	4	2.50	*Dronalen Plus*
Genteal	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	1	1.95	*In a Wink Moisturising*
Genteal gel	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	1	1.95	*HPMC PAA*
Glucophage	Tablet 500 mg	100	0.87	*APO-Metformin 500; Chem mart Metformin; Diabex; Diaformin; Formet 500; GenRx Metformin; Glucobete 500; Metformin 500; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin*
	Tablet 850 mg	60	0.87	*APO-Metformin 850; Chem mart Metformin; Diabex 850; Diaformin 850; Formet 850; GenRx Metformin; Glucobete 850; Metformin 850; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin*
Gopten	Capsule 500 micrograms	28	1.39	*APO-Trandolapril; Dolapril 0.5; Tranalpha; Trandolapril-DP; Trandolapril generichealth*
	Capsule 1 mg	28	1.41	*APO-Trandolapril; Dolapril 1; Tranalpha; Trandolapril-DP; Trandolapril generichealth*
	Capsule 2 mg	28	1.40	*APO-Trandolapril; Dolapril 2; Tranalpha; Trandolapril-DP; Trandolapril generichealth*
	Capsule 4 mg	28	1.42	*APO-Trandolapril; Dolapril 4; Tranalpha; Trandolapril-DP; Trandolapril generichealth*
Imdur 120 mg	Tablet 120 mg (sustained release)	30	2.55	*Monodur 120 mg*
Imdur Durule	Tablet 60 mg (sustained release)	30	2.41	*Chem mart Isosorbide Mononitrate; Duride; GenRx Isosorbide Mononitrate; Imtrate 60 mg; Isomonit; Monodur 60 mg; Terry White Chemists Isosorbide Mononitrate*
Imigran	Tablet 50 mg (as succinate)	4	1.84	*APO-Sumatriptan; Chem mart Sumatriptan; Pharmacor Sumatriptan 50; Sumagran 50; Sumatab;*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
				Sumatriptan-GA; Sumatriptan generichealth; Terry White Chemists Sumatriptan
Imodium	Capsule 2 mg	12	0.89	*Gastro-Stop Loperamide*
Indocid	Capsule 25 mg	100	2.02	*Arthrexin*
Isoptin	Tablet 40 mg	100	0.73	*Anpec 40*
	Tablet 80 mg	100	0.71	*Anpec 80*
Isoptin 180 SR	Tablet 180 mg (sustained release)	30	2.16	*Cordilox 180 SR*
Isoptin SR	Tablet 240 mg (sustained release)	30	2.15	*Cordilox SR*
Keflex	Capsule 250 mg	20	2.03	*Cefalexin Sandoz; Cephalexin generichealth; Cephalexin-PS; Cephatrust 250; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Pharmacor Cephalexin 250; Rancef; Terry White Chemists Cephalexin*
	Capsule 500 mg	20	2.73	*Cefalexin Sandoz; Cephabell; Cephalexin generichealth; Cephalexin-PS; Cephatrust 500; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 500; Pharmacor Cephalexin 500; Rancef; Terry White Chemists Cephalexin*
	Granules for syrup 125 mg per 5 mL, 100 mL	1	2.20	*APO-Cephalexin; Cefalexin Sandoz; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 125; Terry White Chemists Cephalexin*
	Granules for syrup 250 mg per 5 mL, 100 mL	1	2.70	*APO-Cephalexin; Cefalexin Sandoz; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Terry White Chemists Cephalexin*
Kenacomb Otic	Ear drops 1 mg-2.5 mg (base)- 250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 7.5 mL	1	1.95	*Otocomb Otic*
	Ear ointment 1 mg-2.5 mg (base)- 250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 5 g	1	1.95	*Otocomb Otic*
Klacid	Tablet 250 mg	14	1.50	*APO-Clarithromycin; Chem mart Clarithromycin; Clarac; Clarihexal; Clarithro 250; GenRx Clarithromycin; Kalixocin; Terry White Chemists Clarithromycin*
Lacri-Lube	Pack containing 2 tubes compound eye ointment 3.5 g	1	2.12	*Ircal*
Lamictal	Tablet 5 mg	56	1.85	*Lamogine; Seaze 5*
	Tablet 25 mg	56	1.86	*APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine-PS; Lamotrigine Sandoz; Lamotrust 25; Seaze 25; Torlemo DT 25*
	Tablet 50 mg	56	2.14	*APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine-PS; Lamotrigine Sandoz; Lamotrust 50; Seaze 50; Torlemo DT 50*
	Tablet 100 mg	56	1.69	*APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine-PS; Lamotrigine Sandoz; Lamotrust 100; Seaze 100; Torlemo DT 100*
	Tablet 200 mg	56	1.85	*APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine-PS; Lamotrigine Sandoz; Lamotrust 200; Seaze 200; Torlemo DT 200*
Lanoxin	Tablet 250 micrograms	100	2.94	*Sigmaxin*
Lanoxin-PG	Tablet 62.5 micrograms	200	2.95	*Sigmaxin-PG*
Lasix	Tablet 40 mg	100	2.00	*Chem mart Frusemide; Frusax; Frusemide-PS; Frusemide Sandoz; Frusid; GenRx Frusemide; Terry White*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
				Chemists Frusemide; Uremide
Lasix-M	Tablet 20 mg	100	1.60	*Chem mart Frusemide; Frusemide-PS; Frusid; GenRx Frusemide; Terry White Chemists Frusemide*
Lexapro	Tablet 10 mg (as oxalate)	28	4.70	*APO-Escitalopram; Chem mart Escitalopram; Escicor 10; Escitalopram-DRLA; Escitalopram GA; Escitalopram generichealth; Esipram; Esitalo; Lexam 10; LoxaLate; Pharmacor Escitalopram 10; Terry White Chemists Escitalopram*
	Tablet 20 mg (as oxalate)	28	6.85	*APO-Escitalopram; Chem mart Escitalopram; Escicor 20; Escitalopram-DRLA; Escitalopram GA; Escitalopram generichealth; Esipram; Esitalo; Lexam 20; LoxaLate; Pharmacor Escitalopram 20; Terry White Chemists Escitalopram*
Lioresal 10	Tablet 10 mg	100	1.50	*Chem mart Baclofen; Clofen 10; GenRx Baclofen; Stelax 10; Terry White Chemists Baclofen*
Lioresal 25	Tablet 25 mg	100	1.29	*Chem mart Baclofen; Clofen 25; GenRx Baclofen; Stelax 25; Terry White Chemists Baclofen*
Lipex 10	Tablet 10 mg	30	1.76	*APO-Simvastatin; Auro-Simvastatin 10; Chem mart Simvastatin; GenRx Simvastatin; Pharmacor Simvastatin 10; Ransim; Simvacor 10; Simvahexal; Simvar 10; Simvastatin-DP; Simvastatin-GA 10; Simvastatin generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 10; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat; Zocor*
Lipex 20	Tablet 20 mg	30	1.76	*APO-Simvastatin; Auro-Simvastatin 20; Chem mart Simvastatin; GenRx Simvastatin; Pharmacor Simvastatin 20; Ransim; Simvacor 20; Simvahexal; Simvar 20; Simvastatin-DP; Simvastatin-GA 20; Simvastatin generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 20; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat; Zocor*
Lipex 40	Tablet 40 mg	30	2.03	*APO-Simvastatin; Auro-Simvastatin 40; Chem mart Simvastatin; GenRx Simvastatin; Pharmacor Simvastatin 40; Ransim; Simvacor 40; Simvahexal; Simvar 40; Simvastatin-DP; Simvastatin-GA 40; Simvastatin generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 40; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat; Zocor*
Lipex 80	Tablet 80 mg	30	1.84	*APO-Simvastatin; Auro-Simvastatin 80; Chem mart Simvastatin; GenRx Simvastatin; Pharmacor Simvastatin 80; Ransim; Simvacor 80; Simvar 80; Simvastatin-DP; Simvastatin-GA 80; Simvastatin generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 80; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat; Zocor*
Liquifilm Forte	Eye drops 30 mg per mL (3%), 15 mL	1	5.59	*PVA Forte*
Liquifilm Tears	Eye drops 14 mg per mL (1.4%), 15 mL	1	1.60	*PVA Tears*
Lomotil	Tablet 2.5 mg-25 micrograms	20	1.72	*Lofenoxal*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Lopid	Tablet 600 mg	60	1.98	*Ausgem; Chem mart Gemfibrozil; Gemhexal; GenRx Gemfibrozil; Jezil; Lipazil 600 mg; Lipigem; Pharmacor Gemfibrozil 600; Terry White Chemists Gemfibrozil*
Losec Tablets	Tablet 20 mg (as magnesium)	30	2.23	*Acimax Tablets; Omepral*
Luvox	Tablet containing fluvoxamine maleate 50 mg	30	2.30	*APO-Fluvoxamine; Faverin 50; Fluvoxamine GA; Movox 50; Voxam*
	Tablet containing fluvoxamine maleate 100 mg	30	2.30	*APO-Fluvoxamine; Faverin 100; Fluvoxamine GA; Movox 100; Voxam*
Maxamox	Tablet 1 g	14	0.73	*Amoxycillin Sandoz*
Microgynon 30 ED	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	13.59	*Levlen ED*
Minidiab	Tablet 5 mg	100	3.83	*Melizide*
Minomycin-50	Tablet 50 mg	60	1.89	*Akamin 50*
Mobic	Tablet 7.5 mg	30	1.76	*Chem mart Meloxicam 7.5 mg; GenRx Meloxicam; Meloxibell; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Movalis 7.5; Moxicam 7.5; Pharmacor Meloxicam 7.5; Terry White Chemists Meloxicam 7.5 mg*
	Tablet 15 mg	30	1.76	*Chem mart Meloxicam 15 mg; GenRx Meloxicam; Meloxibell; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Movalis 15; Moxicam 15; Pharmacor Meloxicam 15; Terry White Chemists Meloxicam 15 mg*
Mogadon	Tablet 5 mg	50	2.90	*Alodorm*
	Tablet 5 mg	25	1.45	*Alodorm*
Naprosyn	Tablet 250 mg	100	2.24	*Inza 250*
	Tablet 500 mg	50	1.30	*Inza 500*
Naprosyn SR1000	Tablet 1 g (sustained release)	28	1.29	*Proxen SR 1000*
Naprosyn SR750	Tablet 750 mg (sustained release)	28	1.22	*Proxen SR 750*
Natrilix	Tablet 2.5 mg	90	2.43	*Chem mart Indapamide; Dapa-Tabs; GenRx Indapamide; Indapamide-GA; Indapamide Sandoz; Insig; Terry White Chemists Indapamide*
Neoral 100	Capsule 100 mg	60	3.00	*Cicloral*
Neoral 50	Capsule 50 mg	60	2.50	*Cicloral*
Neurontin	Capsule 100 mg	100	0.68	*APO-Gabapentin; DBL Gabapentin; Gabatine 100; Nupentin 100*
	Capsule 300 mg	100	0.61	*DBL Gabapentin; Gabapentin 300; Gabapentin-GA; Gabapentin Sandoz; Gabatine 300; Gantin; GenRx Gabapentin; Nupentin 300*
	Capsule 400 mg	100	0.68	*DBL Gabapentin; Gabapentin 400; Gabapentin Sandoz; Gabatine 400; Gantin; GenRx Gabapentin; Nupentin 400*
	Tablet 600 mg	100	0.68	*Gabaran; Gabatine 600; GenRx Gabapentin; Nupentin Tabs; Pharmacor Gabapentin 600*
	Tablet 800 mg	100	0.67	*Gabaran; Gabatine 800; Gantin; GenRx Gabapentin; Nupentin Tabs; Pharmacor Gabapentin 800*
Nolvadex-D	Tablet 20 mg (base)	60	3.62	*Genox 20; GenRx Tamoxifen; Tamosin; Tamoxen 20 mg; Tamoxifen Sandoz*
Nordette 28	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	13.55	*Monofeme 28*
Noriday 28 Day	Tablets 350 micrograms, 28	4	3.88	*Locilan 28 Day*
Normison	Tablet 10 mg	25	1.21	*APO-Temazepam; Temaze; Temtabs*
	Tablet 10 mg	50	2.42	*APO-Temazepam; Temaze; Temtabs*
Noroxin	Tablet 400 mg	14	2.66	*Chem mart Norfloxacin; GenRx Norfloxacin; Norfloxacin-GA; Norfloxacin Sandoz; Nufloxib; Roxin; Terry White Chemists Norfloxacin*
Norvasc	Tablet 5 mg (as besylate)	30	1.92	*Amlodipine-DRLA; Amlodipine-GA; Amlodipine generichealth; Amlodipine Pfizer; Amlodipine Sandoz; APO-Amlodipine; Auro-Amlodipine 5; Chem mart Amlodipine; Nordip; Norvapine;*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
	Tablet 10 mg (as besylate)	30	2.80	*Ozlodip; Pharmacor Amlodipine 5; Terry White Chemists Amlodipine Amlodipine-DRLA; Amlodipine-GA; Amlodipine generichealth; Amlodipine Pfizer; Amlodipine Sandoz; APO-Amlodipine; Auro-Amlodipine 10; Chem mart Amlodipine; Nordip; Norvapine; Ozlodip; Pharmacor Amlodipine 10; Terry White Chemists Amlodipine*
Oroxine	Tablet equivalent to 50 micrograms anhydrous thyroxine sodium	200	2.21	*Eutroxsig*
	Tablet equivalent to 75 micrograms anhydrous thyroxine sodium	200	2.27	*Eutroxsig*
	Tablet equivalent to 100 micrograms anhydrous thyroxine sodium	200	2.21	*Eutroxsig*
	Tablet equivalent to 200 micrograms anhydrous thyroxine sodium	200	2.21	*Eutroxsig*
Orudis SR 200	Capsule 200 mg (sustained release)	28	2.21	*Oruvail SR*
Panadeine Forte	Tablet 30 mg-500 mg	20	1.88	*APO- Paracetamol/Codeine 500/30; Codalgin Forte; Codapane Forte; Comfarol Forte; Prodeine Forte*
	Tablet 30 mg-500 mg	60	5.64	*APO- Paracetamol/Codeine 500/30; Codalgin Forte; Codapane Forte; Comfarol Forte; Prodeine Forte*
Panafcort	Tablet 1 mg	100	0.61	*Predsone*
Panafcortelone	Tablet 1 mg	100	0.44	*Predsolone*
Pepcidine	Tablet 40 mg	30	3.84	*Ausfam 40; Chem mart Famotidine; Famotidine Sandoz; GenRx Famotidine; Pamacid 40; Pepzan; Terry White Chemists Famotidine*
Plendil ER	Tablet 2.5 mg (extended release)	30	4.06	*Felodur ER 2.5 mg*
	Tablet 5 mg (extended release)	30	4.07	*Felodil XR 5; Felodur ER 5 mg*
	Tablet 10 mg (extended release)	30	4.08	*Felodil XR 10; Felodur ER 10 mg*
Pravachol	Tablet containing pravastatin sodium 10 mg	30	1.97	*APO-Pravastatin; Chem mart Pravastatin; Cholstat 10; GenRx Pravastatin; Lipostat 10; Pharmacor Pravastat 10; Pravastatin Actavis 10; Pravastatin-GA 10; Pravastatin generichealth; Pravastatin Sandoz; Pravastatin Winthrop; Terry White Chemists Pravastatin*
	Tablet containing pravastatin sodium 20 mg	30	2.01	*APO-Pravastatin; Chem mart Pravastatin; Cholstat 20; Cholvastin; GenRx Pravastatin; Lipostat 20; Pharmacor Pravastat 20; Pravastatin Actavis 20; Pravastatin-GA 20; Pravastatin generichealth; Pravastatin Sandoz; Pravastatin Winthrop; Terry White Chemists Pravastatin*
	Tablet containing pravastatin sodium 40 mg	30	2.42	*APO-Pravastatin; Chem mart Pravastatin; Cholstat 40; Cholvastin; GenRx Pravastatin; Lipostat 40; Pharmacor Pravastat 40; Pravastatin Actavis 40; Pravastatin-GA 40; Pravastatin generichealth; Pravastatin Sandoz; Pravastatin Winthrop; Terry White Chemists Pravastatin*
	Tablet containing pravastatin sodium 80 mg	30	2.17	*APO-Pravastatin; Chem mart Pravastatin; Lipostat 80; Pravastatin-GA 80; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin*
Prinivil 10	Tablet 10 mg	30	2.94	*APO-Lisinopril; Chem mart Lisinopril; Fibsol 10; GenRx Lisinopril; Lisinopril 10; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril-PS; Lisinopril Ranbaxy; Lisinopril Sandoz; Lisodur; Terry White Chemists Lisinopril; Zestril*
Prinivil 20	Tablet 20 mg	30	2.94	*APO-Lisinopril; Chem mart Lisinopril;*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
				Fibsol 20; GenRx Lisinopril; Lisinopril 20; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril-PS; Lisinopril Ranbaxy; Lisinopril Sandoz; Lisodur; Terry White Chemists Lisinopril; Zestril
Prinivil 5	Tablet 5 mg	30	2.96	*APO-Lisinopril; Chem mart Lisinopril; Fibsol 5; GenRx Lisinopril; Lisinopril 5; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril-PS; Lisinopril Ranbaxy; Lisinopril Sandoz; Lisodur; Terry White Chemists Lisinopril; Zestril*
Provera	Tablet 10 mg	100	1.53	*Ralovera*
	Tablet 5 mg	56	1.64	*Ralovera*
	Tablet 10 mg	30	1.64	*Medroxyprogesterone Sandoz; Ralovera*
Prozac 20	Capsule 20 mg (as hydrochloride)	28	3.53	*Auscap; Chem mart Fluoxetine; Fluoxetine 20; Fluoxetine-GA; Fluoxetine generichealth; Fluoxetine-PS; Fluoxetine RBX; Fluoxetine Sandoz; GenRx Fluoxetine; Lovan; Terry White Chemists Fluoxetine; Zactin*
Prozac Tab	Tablet, dispersible, 20 mg (as hydrochloride)	28	3.53	*Lovan 20 Tab; Zactin Tablet*
Redipred	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	1	1.77	*PredMix*
Renitec	Tablet containing enalapril maleate 10 mg	30	3.49	*Acetec; Auspril; Chem mart Enalapril; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Terry White Chemists Enalapril*
Renitec 20	Tablet containing enalapril maleate 20 mg	30	3.49	*Acetec; Auspril; Chem mart Enalapril; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Terry White Chemists Enalapril*
Renitec M	Tablet containing enalapril maleate 5 mg	30	3.49	*Acetec; Auspril; Chem mart Enalapril; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Terry White Chemists Enalapril*
Rivotril	Tablet 500 micrograms	100	1.71	*Paxam 0.5*
	Tablet 500 micrograms	200	3.42	*Paxam 0.5*
	Tablet 2 mg	100	1.93	*Paxam 2*
	Tablet 2 mg	200	3.86	*Paxam 2*
Roaccutane	Capsule 20 mg	60	1.63	*APO-Isotretinoin; GenRx Isotretinoin; Oratane; Rocta 20*
Rulide	Tablet 150 mg	10	1.71	*APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 150; Roximycin; Roxithromycin-GA; Roxithromycin Sandoz; Terry White Chemists Roxithromycin*
	Tablet 300 mg	5	1.71	*APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 300; Roximycin; Roxithromycin-GA; Roxithromycin Sandoz; Terry White Chemists Roxithromycin*
Salazopyrin-EN	Tablet 500 mg (enteric coated)	200	1.84	*Pyralin EN*
Septrin Forte	Tablet 160 mg-800 mg	10	1.46	*Bactrim DS; Resprim Forte*
Serepax	Tablet 15 mg	25	2.69	*Alepam 15*
	Tablet 15 mg	50	5.38	*Alepam 15*
	Tablet 30 mg	25	2.69	*Alepam 30; APO-Oxazepam; Murelax*
	Tablet 30 mg	50	5.38	*Alepam 30; APO-Oxazepam; Murelax*
Sigmacort	Cream 10 mg per g (1%), 30 g	1	2.69	*Cortic-DS 1%*
	Cream 10 mg per g (1%), 50 g	1	2.70	*Cortic-DS 1%*
	Topical ointment 10 mg per g (1%), 30 g	1	2.69	*Cortic-DS 1%*
	Topical ointment 10 mg per g (1%), 50 g	1	2.70	*Cortic-DS 1%*
Sinemet	Tablet 250 mg-25 mg	100	2.92	*Levo/Carbidopa Sandoz*
Sinemet 100/25	Tablet 100 mg-25 mg	100	5.19	*Kinson*
Slow-K	Tablet 600 mg (sustained release)	200	2.94	*Duro-K*
Sofradex	Ear drops 500 micrograms-5 mg-50 micrograms per mL, 8 mL	1	1.91	*Otodex*
Sotacor	Tablet 80 mg	60	3.40	*GenRx Sotalol; Solavert; Sotalol Sandoz*
	Tablet 160 mg	60	3.40	*Cardol; Chem mart Sotalol; GenRx Sotalol; Solavert; Sotalol Sandoz; Terry White Chemists Sotalol*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Stemetil	Tablet containing prochlorperazine maleate 5 mg	25	3.45	*APO-Prochlorperazine; Pharmacor Prozine 5; ProCalm; Prochlorperazine-GA; Prochlorperazine GH; Prochlorperazine-PS; Stemzine*
Tazac	Capsule 150 mg	60	5.32	*Nizac; Tacidine*
	Capsule 300 mg	30	5.32	*Nizac; Tacidine*
Tears Naturale	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	1	1.77	*Poly-Tears*
Tegretol 100	Tablet 100 mg	200	2.96	*Carbamazepine Sandoz*
Tegretol 200	Tablet 200 mg	200	2.96	*Carbamazepine Sandoz; Teril*
Tenormin	Tablet 50 mg	30	2.21	*APO-Atenolol; Atenolol-GA; Atenolol generichealth; Atenolol-PS; Atenolol Sandoz; Chem mart Atenolol; Noten; Tensig; Terry White Chemists Atenolol*
Timoptol	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	1	3.03	*Tenopt*
	Eye drops 5 mg (base) per mL (0.5%), 5 mL	1	3.03	*Tenopt*
Tofranil 10	Tablet 10 mg	50	2.79	*Tolerade 10*
Tofranil 25	Tablet 25 mg	50	2.79	*Tolerade 25*
Tolvon	Tablet 10 mg	50	3.30	*Lumin 10*
	Tablet 20 mg	50	3.30	*Lumin 20*
Tramal	Capsule 50 mg	20	1.83	*APO-Tramadol; Chem mart Tramadol; GA Tramadol 50mg; GenRx Tramadol; Lodam 50; Terry White Chemists Tramadol; Tramadol Sandoz; Tramedo; Zydol*
Tramal SR 100	Tablet 100 mg (twice daily sustained release)	20	3.40	*APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 100mg; Lodam SR 100; Terry White Chemists Tramadol SR; Tramadol Sandoz SR; Tramedo SR 100; Zydol SR 100*
Tramal SR 150	Tablet 150 mg (twice daily sustained release)	20	4.06	*APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 150mg; Lodam SR 150; Terry White Chemists Tramadol SR; Tramadol Sandoz SR; Tramedo SR 150; Zydol SR 150*
Tramal SR 200	Tablet 200 mg (twice daily sustained release)	20	4.59	*APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 200mg; Lodam SR 200; Terry White Chemists Tramadol SR; Tramadol Sandoz SR; Tramedo SR 200; Zydol SR 200*
Trandate	Tablet 100 mg	100	3.13	*Presolol 100*
	Tablet 200 mg	100	3.14	*Presolol 200*
Triphasil 28	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	4	13.55	*Trifeme 28*
Triprim	Tablet 300 mg	7	1.89	*Alprim*
Triquilar ED	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	4	13.59	*Logynon ED*
Valium	Tablet 2 mg	50	0.82	*Antenex 2; APO-Diazepam; Ranzepam; Valpam 2*
	Tablet 5 mg	50	0.85	*Antenex 5; APO-Diazepam; Diazepam-GA; Ranzepam; Valpam 5*
Vastin	Capsule 20 mg (as sodium)	28	3.09	*Lescol*
	Capsule 40 mg (as sodium)	28	3.36	*Lescol*
Ventolin CFC-free	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	2.32	*Airomir; APO-Salbutamol Inhaler; Asmol CFC-free*
Ventolin Nebules	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	2	1.34	*Asmol 2.5 uni-dose; Butamol 2.5; GenRx Salbutamol; Pharmacor Salbutamol 2.5; Salbutamol-GA; Salbutamol Sandoz*
	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	2	1.36	*Asmol 5 uni-dose; Butamol 5; GenRx Salbutamol; Pharmacor Salbutamol 5; Salbutamol-GA; Salbutamol Sandoz*
Vibra-Tabs	Tablet 50 mg (as hydrochloride)	25	1.20	*Doxy-50; Doxylin 50*
Viscotears	Eye gel 2 mg per g (0.2%), 10 g	1	1.50	*PAA*
Visken 15	Tablet 15 mg	50	2.57	*Barbloc 15*
Voltaren 25	Tablet 25 mg (enteric coated)	100	2.32	*APO-Diclofenac; Chem mart Diclofenac; Clonac 25; Diclofenac-GA; Diclofenac Sandoz; Fenac 25; Terry White Chemists Diclofenac*
Voltaren 50	Tablet 50 mg (enteric coated)	50	2.34	*APO-Diclofenac; Chem mart*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
				Diclofenac; Clonac 50; Diclofenac-GA; Diclofenac Sandoz; Fenac; Terry White Chemists Diclofenac
Xanax	Tablet 250 micrograms	50	0.83	*Alprax 0.25; Alprazolam Sandoz; Kalma 0.25*
	Tablet 500 micrograms	50	0.87	*Alprax 0.5; Alprazolam Sandoz; Kalma 0.5*
	Tablet 1 mg	50	1.04	*Alprax 1; Alprazolam Sandoz; Chem mart Alprazolam; GenRx Alprazolam; Kalma 1; Ralozam; Terry White Chemists Alprazolam*
Xanax Tri-Score	Tablet 2 mg	50	1.25	*Alprax 2; Alprazolam Sandoz; Chem mart Alprazolam; GenRx Alprazolam; Kalma 2; Ralozam; Terry White Chemists Alprazolam*
Zanidip	Tablet 10 mg	28	2.66	*APO-Lercanidipine; Chem mart Lercanidipine; Lercadip; Lercan; Lercanidipine Sandoz; Terry White Chemists Lercanidipine; Zircol*
	Tablet 20 mg	28	2.64	*APO-Lercanidipine; Chem mart Lercanidipine; Lercadip; Lercan; Lercanidipine Sandoz; Terry White Chemists Lercanidipine; Zircol*
Zantac	Tablet 150 mg (base)	60	2.35	*Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranitidine-PS; Ranitidine Sandoz; Ranoxyl; Terry White Chemists Ranitidine; Ulcaid*
	Tablet 300 mg (base)	30	2.35	*Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranitidine Sandoz; Terry White Chemists Ranitidine; Ulcaid*
Zestril	Tablet 5 mg	30	1.47	*APO-Lisinopril; Chem mart Lisinopril; Fibsol 5; GenRx Lisinopril; Lisinopril 5; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril-PS; Lisinopril Ranbaxy; Lisinopril Sandoz; Lisodur; Prinivil 5; Terry White Chemists Lisinopril*
	Tablet 10 mg	30	1.47	*APO-Lisinopril; Chem mart Lisinopril; Fibsol 10; GenRx Lisinopril; Lisinopril 10; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril-PS; Lisinopril Ranbaxy; Lisinopril Sandoz; Lisodur; Prinivil 10; Terry White Chemists Lisinopril*
	Tablet 20 mg	30	1.47	*APO-Lisinopril; Chem mart Lisinopril; Fibsol 20; GenRx Lisinopril; Lisinopril 20; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril-PS; Lisinopril Ranbaxy; Lisinopril Sandoz; Lisodur; Prinivil 20; Terry White Chemists Lisinopril*
Zocor	Tablet 5 mg	30	1.76	*Simvahexal; Simvastatin Sandoz; Zimstat*
	Tablet 10 mg	30	1.76	*APO-Simvastatin; Auro-Simvastatin 10; Chem mart Simvastatin; GenRx Simvastatin; Lipex 10; Pharmacor Simvastatin 10; Ransim; Simvacor 10; Simvahexal; Simvar 10; Simvastatin-DP; Simvastatin-GA 10; Simvastatin generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 10; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat*
	Tablet 20 mg	30	1.76	*APO-Simvastatin; Auro-Simvastatin 20; Chem mart Simvastatin; GenRx Simvastatin; Lipex 20; Pharmacor Simvastatin 20; Ransim; Simvacor 20; Simvahexal; Simvar 20; Simvastatin-DP; Simvastatin-GA 20; Simvastatin*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
				generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 20; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat
	Tablet 40 mg	30	2.03	*APO-Simvastatin; Auro-Simvastatin 40; Chem mart Simvastatin; GenRx Simvastatin; Lipex 40; Pharmacor Simvastatin 40; Ransim; Simvacor 40; Simvahexal; Simvar 40; Simvastatin-DP; Simvastatin-GA 40; Simvastatin generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 40; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat*
	Tablet 80 mg	30	1.84	*APO-Simvastatin; Auro-Simvastatin 80; Chem mart Simvastatin; GenRx Simvastatin; Lipex 80; Pharmacor Simvastatin 80; Ransim; Simvacor 80; Simvar 80; Simvastatin-DP; Simvastatin-GA 80; Simvastatin generichealth; Simvastatin Pfizer; Simvastatin Sandoz; Simvastatin-Spirit 80; Simvastatin Winthrop; Synthon Simvastatin; Terry White Chemists Simvastatin; Zimstat*
Zoloft	Tablet 50 mg (as hydrochloride)	30	0.77	*Auro-Sertraline 50; Chem mart Sertraline; Eleva 50; GenRx Sertraline; Sertra 50; Sertracor 50; Sertraline 50; Sertraline-DRLA; Sertraline-GA; Sertraline generichealth; Sertraline Pfizer; Sertraline Sandoz; Setrona; Terry White Chemists Sertraline; Xydep 50*
	Tablet 100 mg (as hydrochloride)	30	0.77	*Auro-Sertraline 100; Chem mart Sertraline; Eleva 100; GenRx Sertraline; Sertra 100; Sertracor 100; Sertraline 100; Sertraline-DRLA; Sertraline-GA; Sertraline generichealth; Sertraline Pfizer; Sertraline Sandoz; Setrona; Terry White Chemists Sertraline; Xydep 100*
Zovirax 200 mg	Tablet 200 mg	50	4.10	*Acihexal; Acyclo-V 200; GenRx Aciclovir; Lovir*
	Tablet 200 mg	90	3.06	*Aciclovir 200; Aciclovir GH; Acihexal; Acyclo-V 200; Chem mart Aciclovir; GenRx Aciclovir; Lovir; Ozvir; Terry White Chemists Aciclovir*
Zovirax 800 mg	Tablet 800 mg	35	1.49	*Aciclovir 800; Acihexal; Acyclo-V 800; GenRx Aciclovir*
Zyban	Tablet 150 mg (sustained release)	30	0.80	*Prexaton*
	Tablet 150 mg (sustained release)	90	0.81	*Prexaton*
Zyloprim	Tablet 100 mg	200	2.85	*Allopurinol Sandoz; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Progout 100; Terry White Chemists Allopurinol*
	Tablet 300 mg	60	2.85	*Allopurinol Sandoz; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Progout 300; Terry White Chemists Allopurinol*