Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 May 2012

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 May 2012. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

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 – Brand

8511Y *Densate 70, DO* – **Alendronate Sodium**, Tablet equivalent to 70 mg alendronic acid

8179L *Anastrozole Synthon, ZT* – **Anastrozole**, Tablet 1 mg

8179L *Arianna, AF* – **Anastrozole**, Tablet 1 mg

8604W *Beprol 2.5, DO* – **Bisoprolol Fumarate**, Tablet 2.5 mg

8605X *Beprol 5, DO* – **Bisoprolol Fumarate**, Tablet 5 mg

8606Y *Beprol 10, DO* – **Bisoprolol Fumarate**, Tablet 10 mg

8245Y *Letrozole-Synthon, ZT* – **Letrozole**, Tablet 2.5 mg

2430X *Glucobete 500, DO* – **Metformin Hydrochloride**, Tablet 500 mg

1801T *Glucobete 850, DO* – **Metformin Hydrochloride**, Tablet 850 mg

8607B *Glucobete 1000, DO* – **Metformin Hydrochloride**, Tablet 1 g

8513C *Aurozapine 30, DO* – **Mirtazapine**, Tablet 30 mg

8883M *Aurozapine 45, DO* – **Mirtazapine**, Tablet 45 mg

8855C *Milivin OD 15, DO* – **Mirtazapine**, Tablet 15 mg (orally disintegrating)

8856D *Milivin OD 30, DO* – **Mirtazapine**, Tablet 30 mg (orally disintegrating)

8857E *Milivin OD 45, DO* – **Mirtazapine**, Tablet 45 mg (orally disintegrating)

8650G *Pharmacor Mycophenolate 500, CR* – **Mycophenolate Mofetil**, Tablet 500 mg

3381Y *Olanzapine ODT generichealth 5, GQ* – **Olanzapine**, Tablet 5 mg (orally disintegrating)

3381Y *Olanzapine Sandoz ODT 5, SZ* – **Olanzapine**, Tablet 5 mg (orally disintegrating)

3382B *Olanzapine ODT generichealth 10, GQ* – **Olanzapine**, Tablet 10 mg (orally disintegrating)

3382B *Olanzapine Sandoz ODT 10, SZ* – **Olanzapine**, Tablet 10 mg (orally disintegrating)

1024X *Olanzapine-Synthon, ZT* – **Olanzapine**, Tablet 2.5 mg (as benzoate)

1037N *Olanzapine-Synthon, ZT* – **Olanzapine**, Tablet 5 mg (as benzoate)

1041T *Olanzapine-Synthon, ZT* – **Olanzapine**, Tablet 7.5 mg (as benzoate)

1042W *Olanzapine-Synthon, ZT* – **Olanzapine**, Tablet 10 mg (as benzoate)

1594X *Zilfojim 4, DO* – **Ondansetron**, Tablet 4 mg (as hydrochloride dihydrate)

1595Y *Zilfojim 8, DO* – **Ondansetron**, Tablet 8 mg (as hydrochloride dihydrate)

8399C *Torzole 20, TA* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 20 mg pantoprazole

8007K *Torzole 40, TA* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole

8008L *Torzole 40, TA* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole

2833D *Pravastatin Actavis 10, TA* – **Pravastatin**, Tablet containing pravastatin sodium 10 mg

9237E *Pravastatin Actavis 10, TA* – **Pravastatin**, Tablet containing pravastatin sodium 10 mg

2834E *Pravastatin Actavis 20, TA* – **Pravastatin**, Tablet containing pravastatin sodium 20 mg

9238F *Pravastatin Actavis 20, TA* – **Pravastatin**, Tablet containing pravastatin sodium 20 mg

8197K *Pravastatin Actavis 40, TA* – **Pravastatin**, Tablet containing pravastatin sodium 40 mg

9239G *Pravastatin Actavis 40, TA* – **Pravastatin**, Tablet containing pravastatin sodium 40 mg

8456C *Seronia 25, QA* – **Quetiapine**, Tablet 25 mg (as fumarate)

8456C *Syquet, AF* – **Quetiapine**, Tablet 25 mg (as fumarate)

8457D *Seronia 100, QA* – **Quetiapine**, Tablet 100 mg (as fumarate)

8457D *Syquet, AF* – **Quetiapine**, Tablet 100 mg (as fumarate)

8458E *Seronia 200, QA* – **Quetiapine**, Tablet 200 mg (as fumarate)

8458E *Syquet, AF* – **Quetiapine**, Tablet 200 mg (as fumarate)

8580N *Seronia 300, QA* – **Quetiapine**, Tablet 300 mg (as fumarate)

8580N *Syquet, AF* – **Quetiapine**, Tablet 300 mg (as fumarate)

1944H *Ramipril Tabs Pfizer, FZ* – **Ramipril**, Tablet 1.25 mg

1944H *Vascalace 1.25, DO* – **Ramipril**, Tablet 1.25 mg

1945J *Ramipril Tabs Pfizer, FZ* – **Ramipril**, Tablet 2.5 mg

1945J *Vascalace 2.5, DO* – **Ramipril**, Tablet 2.5 mg

1946K *Ramipril Tabs Pfizer, FZ* – **Ramipril**, Tablet 5 mg

1946K *Vascalace 5, DO* – **Ramipril**, Tablet 5 mg

1316G *Ramipril Tabs Pfizer, FZ* – **Ramipril**, Tablet 10 mg

1316G *Vascalace 10, DO* – **Ramipril**, Tablet 10 mg

8787L *Risperidone Actavis 0.5, TA* – **Risperidone**, Tablet 0.5 mg

8869T *Risperidone Actavis 0.5, TA* – **Risperidone**, Tablet 0.5 mg

8789N *Risperidone Actavis 1, TA* – **Risperidone**, Tablet 1 mg

3169T *Risperidone Actavis 1, TA* – **Risperidone**, Tablet 1 mg

9079W *Risperidone Actavis 2, TA* – **Risperidone**, Tablet 2 mg

3170W *Risperidone Actavis 2, TA* – **Risperidone**, Tablet 2 mg

3171X *Risperidone Actavis 3, TA* – **Risperidone**, Tablet 3 mg

3172Y *Risperidone Actavis 4, TA* – **Risperidone**, Tablet 4 mg

2011W *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 10 mg

9242K *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 10 mg

2012X *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 20 mg

9243L *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 20 mg

8173E *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 40 mg

8173E *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 40 mg

9244M *Simvastatin Sandoz, SZ* – **Simvastatin**, Tablet 40 mg

9244M *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 40 mg

8313M *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 80 mg

9245N *Synthon Simvastatin, ZT* – **Simvastatin**, Tablet 80 mg

5480K *Shilova 500, DO* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

8134D *Shilova 500, DO* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

8868R *Altven, FZ* – **Venlafaxine Hydrochloride**, Capsule 37.5 mg (base) (modified release)

8301X *Altven, FZ* – **Venlafaxine Hydrochloride**, Capsule 75 mg (base) (modified release)

8302Y *Altven, FZ* – **Venlafaxine Hydrochloride**, Capsule 150 mg (base) (modified release)

Addition – Equivalence Indicator

8855C *Avanza SolTab, MK* – **Mirtazapine**, Tablet 15 mg (orally disintegrating)

8856D *Avanza SolTab, MK* – **Mirtazapine**, Tablet 30 mg (orally disintegrating)

8857E *Avanza SolTab, MK* – **Mirtazapine**, Tablet 45 mg (orally disintegrating)

Deletions

Deletion – Item

2891E **Glucose Indicator—blood**, Test strips, 50 *(Advantage II)*

9258G **Glucose Indicator—blood**, Test strips, 50 *(Advantage II)*

1658G **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL *(Naprosyn)*

5397C **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL *(Naprosyn)* **(Palliative Care)**

5398D **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL *(Naprosyn)* **(Palliative Care)**

5328K **Promethazine Hydrochloride**, Tablet 10 mg *(Phenergan)* **(Palliative Care)**

5325G **Promethazine Hydrochloride**, Tablet 10 mg *(Phenergan)* **(Palliative Care)**

5329L **Promethazine Hydrochloride**, Tablet 25 mg *(Phenergan)* **(Palliative Care)**

5326H **Promethazine Hydrochloride**, Tablet 25 mg *(Phenergan)* **(Palliative Care)**

5330M **Promethazine Hydrochloride**, Oral liquid 5 mg per 5 mL, 100 mL *(Phenergan)* **(Palliative Care)**

5327J **Promethazine Hydrochloride**, Oral liquid 5 mg per 5 mL, 100 mL *(Phenergan)* **(Palliative Care)**

Deletion – Brand

8255L *Kredex, MD* – **Carvedilol**, Tablet 3.125 mg

1370D *Enalapril Winthrop, WA* – **Enalapril**, Tablet containing enalapril maleate 5 mg

1368B *Enalapril Winthrop, WA* – **Enalapril**, Tablet containing enalapril maleate 10 mg

2456G *Lisinopril Winthrop, WA* – **Lisinopril**, Tablet 5 mg

2457H *Lisinopril Winthrop, WA* – **Lisinopril**, Tablet 10 mg

2458J *Lisinopril Winthrop, WA* – **Lisinopril**, Tablet 20 mg

8226Y *Pfizer Australia Pty Ltd, PF* – **Ondansetron**, I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL

1596B *Pfizer Australia Pty Ltd, PF* – **Ondansetron**, I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL

8227B *Pfizer Australia Pty Ltd, PF* – **Ondansetron**, I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL

1597C *Pfizer Australia Pty Ltd, PF* – **Ondansetron**, I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL

2236Q *Sertraline Winthrop, WA* – **Sertraline**, Tablet 50 mg (as hydrochloride)

8163P *Topiramate generichealth, GQ* – **Topiramate**, Tablet 25 mg

8164Q *Topiramate generichealth, GQ* – **Topiramate**, Tablet 50 mg

8165R *Topiramate generichealth, GQ* – **Topiramate**, Tablet 100 mg

8166T *Topiramate generichealth, GQ* – **Topiramate**, Tablet 200 mg

Alterations

Alteration – Brand Name

From:

1968N *Filpril, FZ* – **Quinapril**, Tablet 5 mg (as hydrochloride)

To:

1968N *Quinapril Pfizer, FZ* – **Quinapril**, Tablet 5 mg (as hydrochloride)

From:

1969P *Filpril, FZ* – **Quinapril**, Tablet 10 mg (as hydrochloride)

To:

1969P *Quinapril Pfizer, FZ* – **Quinapril**, Tablet 10 mg (as hydrochloride)

From:

1970Q *Filpril, FZ* – **Quinapril**, Tablet 20 mg (as hydrochloride)

To:

1970Q *Quinapril Pfizer, FZ* – **Quinapril**, Tablet 20 mg (as hydrochloride)

Alteration – Manufacturer's Code

		From	*To*
8094B	*Cosudex, SZ* – **Bicalutamide**, Tablet 50 mg	AP	SZ
8844L	*Angiomax, XM* – **Bivalirudin Trifluoroacetate**, Powder for I.V. injection 250 mg (base)	CS	XM
8802G	*Elidel, HM* – **Pimecrolimus**, Cream 10 mg per g (1%), 15 g	NV	HM
8173E	*Simvahexal, HX* – **Simvastatin**, Tablet 40 mg	SZ	HX
9244M	*Simvahexal, HX* – **Simvastatin**, Tablet 40 mg	SZ	HX

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

1419Q **Tocilizumab**, Concentrate for injection 80 mg in 4 mL *(Actemra)* **(Private)**

1476Q **Tocilizumab**, Concentrate for injection 80 mg in 4 mL *(Actemra)* **(Public)**

1423X **Tocilizumab**, Concentrate for injection 200 mg in 10 mL *(Actemra)* **(Private)**

1481Y **Tocilizumab**, Concentrate for injection 200 mg in 10 mL *(Actemra)* **(Public)**

1464C **Tocilizumab**, Concentrate for injection 400 mg in 20 mL *(Actemra)* **(Private)**

1482B **Tocilizumab**, Concentrate for injection 400 mg in 20 mL *(Actemra)* **(Public)**

Addition – Brand

6249X *Lipodox, ZF* – **Doxorubicin Hydrochloride, Pegylated Liposomal**, Suspension for I.V. infusion 20 mg in 10 mL **(Private)**

5705G *Lipodox, ZF* – **Doxorubicin Hydrochloride, Pegylated Liposomal**, Suspension for I.V. infusion 20 mg in 10 mL **(Public)**

6209T *Pharmacor Mycophenolate 500, CR* – **Mycophenolate Mofetil**, Tablet 500 mg **(Private)**

9502D *Pharmacor Mycophenolate 500, CR* – **Mycophenolate Mofetil**, Tablet 500 mg **(Public)**

Deletions

Deletion – Item

5652L **Darunavir**, Tablet 300 mg (as ethanolate) *(Prezista)* **(Public)**

9616D **Darunavir**, Tablet 300 mg (as ethanolate) *(Prezista)* **(Private)**

5736X **Etravirine**, Tablet 100 mg *(Intelence)* **(Public)**

9639H **Etravirine**, Tablet 100 mg *(Intelence)* **(Private)**

REPATRIATION PHARMACEUTICAL BENEFITS

Deletions

Deletion – Item

4072H **Promethazine Hydrochloride**, Tablet 10 mg *(Phenergan)*

4073J **Promethazine Hydrochloride**, Tablet 25 mg *(Phenergan)*

Deletion – Brand

4171M *Panamax Co., SW* – **Codeine Phosphate with Paracetamol**, Tablet 8 mg-500 mg

4419N *Fibre Health Orange Smooth Sugar Free, PP* – **Psyllium Hydrophilic Mucilloid**, Oral powder (orange-flavoured, sugar-free) 283 g

Alterations

Alteration – Brand Name

From:

4050E *Coban, MM* – **Bandage—compression**, Bandage, two layer

To:

4050E *Coban 2, MM* – **Bandage—compression**, Bandage, two layer

Advance Notices

Advance Notices – Deletion of Item

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

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

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

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

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

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.

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.

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 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 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.

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

(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.

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:

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

(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 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

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	

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.

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

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

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.

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.

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 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 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.

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

(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.

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:

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

(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 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

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).

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
1464C	Concentrate for injection 400 mg in 20 mL	1	..	..	978.20	Actemra	RO