Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 August 2012

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 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 August 2012 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$6.52
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.56
	Allowable additional patient charge*	$4.04
Additional Fees (for safety net prices):	Ready-prepared	$1.11
	Extemporaneously-prepared	$1.45
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

1923F **Amino Acid Formula with Vitamins and Minerals without Methionine, Threonine and Valine and low in Isoleucine**, Oral liquid 130 mL, 30 *(MMA/PA cooler)*

1909L **Amino Acid Formula with Vitamins and Minerals without Phenylalanine**, Sachets 34 g, 30 *(PKU express 20)*

1914R **Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine**, Sachets 34 g, 30 *(MSUD express 20)*

2022K **Auranofin**, Capsule 3 mg *(Ridaura)*

2002J **Cefuroxime Axetil**, Powder for oral suspension 125 mg (base) per 5 mL, 70 mL *(Zinnat)* **(Dental)**

5499K **Cefuroxime Axetil**, Powder for oral suspension 125 mg (base) per 5 mL, 70 mL *(Zinnat)*

1954W **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *(Enbrel)*

1963H **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 *(Enbrel)*

1964J **Etanercept**, Injection 50 mg in 1 mL single use auto-injector, 4 *(Enbrel)*

1976B **Icatibant**, Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe *(Firazyr)*

1952R **Rasagiline**, Tablet 1 mg (as mesilate) *(Azilect)*

1418P **Ticagrelor**, Tablet 90 mg *(Brilinta)*

1938B **Triglycerides—medium Chain, Formula**, Compound powder 400 g *(Lipistart)*

Addition – Brand

8202Q *Spren 100, QA* – **Aspirin**, Tablet 100 mg

8213G *Atorvastatin SCP 10, RZ* – **Atorvastatin**, Tablet 10 mg (as calcium)

9230T *Atorvastatin SCP 10, RZ* – **Atorvastatin**, Tablet 10 mg (as calcium)

8214H *Atorvastatin SCP 20, RZ* – **Atorvastatin**, Tablet 20 mg (as calcium)

9231W *Atorvastatin SCP 20, RZ* – **Atorvastatin**, Tablet 20 mg (as calcium)

8215J *Atorvastatin SCP 40, RZ* – **Atorvastatin**, Tablet 40 mg (as calcium)

9232X *Atorvastatin SCP 40, RZ* – **Atorvastatin**, Tablet 40 mg (as calcium)

8521L *Atorvastatin SCP 80, RZ* – **Atorvastatin**, Tablet 80 mg (as calcium)

9233Y *Atorvastatin SCP 80, RZ* – **Atorvastatin**, Tablet 80 mg (as calcium)

8213G *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 10 mg (as calcium)

8214H *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 20 mg (as calcium)

8215J *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 40 mg (as calcium)

8521L *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 80 mg (as calcium)

9230T *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 10 mg (as calcium)

9231W *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 20 mg (as calcium)

9232X *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 40 mg (as calcium)

9233Y *STADA Atorvastatin, TD* – **Atorvastatin**, Tablet 80 mg (as calcium)

8315P *Cefepime Sandoz, SZ* – **Cefepime**, Powder for injection 1 g (as hydrochloride) (solvent required)

8316Q *Cefepime Sandoz, SZ* – **Cefepime**, Powder for injection 2 g (as hydrochloride) (solvent required)

8358X *Plavicor 75, MI* – **Clopidogrel**, Tablet 75 mg (as hydrogen sulfate)

9354H *STADA Clopidogrel, TD* – **Clopidogrel**, Tablet 75 mg (as besilate)

8019C *Cyprocur 100, QA* – **Cyproterone Acetate**, Tablet 100 mg

1313D *Diltiazem Sandoz CD, SZ* – **Diltiazem Hydrochloride**, Capsule 240 mg (controlled delivery)

8480H *Diltiazem Sandoz CD, SZ* – **Diltiazem Hydrochloride**, Capsule 360 mg (controlled delivery)

1370D *Enalapril-PS, FZ* – **Enalapril**, Tablet containing enalapril maleate 5 mg

1368B *Enalapril-PS, FZ* – **Enalapril**, Tablet containing enalapril maleate 10 mg

1369C *Enalapril-PS, FZ* – **Enalapril**, Tablet containing enalapril maleate 20 mg

8770N *APO-Galantamine MR, TX* – **Galantamine Hydrobromide**, Capsule 8 mg (base) (prolonged release)

8771P *APO-Galantamine MR, TX* – **Galantamine Hydrobromide**, Capsule 16 mg (base) (prolonged release)

8772Q *APO-Galantamine MR, TX* – **Galantamine Hydrobromide**, Capsule 24 mg (base) (prolonged release)

8770N *Gamine XR, QA* – **Galantamine Hydrobromide**, Capsule 8 mg (base) (prolonged release)

8771P *Gamine XR, QA* – **Galantamine Hydrobromide**, Capsule 16 mg (base) (prolonged release)

8772Q *Gamine XR, QA* – **Galantamine Hydrobromide**, Capsule 24 mg (base) (prolonged release)

1512N *APO- Hydroxychloroquine, TX* – **Hydroxychloroquine Sulfate**, Tablet 200 mg

1512N *Chem mart Hydroxychloroquine, CH* – **Hydroxychloroquine Sulfate**, Tablet 200 mg

1512N *Terry White Chemists Hydroxychloroquine, TW* – **Hydroxychloroquine Sulfate**, Tablet 200 mg

2436F *Indapamide-PS, FZ* – **Indapamide Hemihydrate**, Tablet 2.5 mg

5552F *APO-Latanoprost, TX* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL **(Optometrical)**

8243W *APO-Latanoprost, TX* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL

5552F *Chem mart Latanoprost, CH* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL **(Optometrical)**

8243W *Chem mart Latanoprost, CH* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL

5552F *Latanoprost Pfizer, FZ* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL **(Optometrical)**

8243W *Latanoprost Pfizer, FZ* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL

5552F *Latanoprost Sandoz, SZ* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL **(Optometrical)**

8243W *Latanoprost Sandoz, SZ* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL

5552F *Terry White Chemists Latanoprost, TW* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL **(Optometrical)**

8243W *Terry White Chemists Latanoprost, TW* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL

8895E *Latanocom, FZ* – **Latanoprost with Timolol Maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL

5553G *Latanocom, FZ* – **Latanoprost with Timolol Maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL **(Optometrical)**

8245Y *Lezole, WQ* – **Letrozole**, Tablet 2.5 mg

8887R *Melox 7.5, GM* – **Meloxicam**, Capsule 7.5 mg

8888T *Melox 15, GM* – **Meloxicam**, Capsule 15 mg

8561N *Meloxicam-PS, FZ* – **Meloxicam**, Tablet 7.5 mg

8562P *Meloxicam-PS, FZ* – **Meloxicam**, Tablet 15 mg

2430X *Formet Aspen 500, AS* – **Metformin Hydrochloride**, Tablet 500 mg

1801T *Formet Aspen 850, AS* – **Metformin Hydrochloride**, Tablet 850 mg

8855C *Remeron SolTab, FR* – **Mirtazapine**, Tablet 15 mg (orally disintegrating)

8856D *Remeron SolTab, FR* – **Mirtazapine**, Tablet 30 mg (orally disintegrating)

8857E *Remeron SolTab, FR* – **Mirtazapine**, Tablet 45 mg (orally disintegrating)

3010K *Norfloxacin-PS, FZ* – **Norfloxacin**, Tablet 400 mg

1024X *STADA Olanzapine, TD* – **Olanzapine**, Tablet 2.5 mg (as benzoate)

1037N *STADA Olanzapine, TD* – **Olanzapine**, Tablet 5 mg (as benzoate)

1041T *STADA Olanzapine, TD* – **Olanzapine**, Tablet 7.5 mg (as benzoate)

1042W *STADA Olanzapine, TD* – **Olanzapine**, Tablet 10 mg (as benzoate)

8333N *Omeprazole-PS, FZ* – **Omeprazole**, Tablet 20 mg

9151P *Simipex 0.125, QA* – **Pramipexole Hydrochloride**, Tablet 125 micrograms

9152Q *Simipex 0.25, QA* – **Pramipexole Hydrochloride**, Tablet 250 micrograms

9153R *Simipex 1, QA* – **Pramipexole Hydrochloride**, Tablet 1 mg

2833D *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 10 mg

2834E *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 20 mg

8197K *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 40 mg

8829Q *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 80 mg

9237E *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 10 mg

9238F *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 20 mg

9239G *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 40 mg

9240H *Pravastatin-PS, FZ* – **Pravastatin**, Tablet containing pravastatin sodium 80 mg

8456C *Quetiapine-Synthon, ZT* – **Quetiapine**, Tablet 25 mg (as fumarate)

8457D *Quetiapine-Synthon, ZT* – **Quetiapine**, Tablet 100 mg (as fumarate)

8458E *Quetiapine-Synthon, ZT* – **Quetiapine**, Tablet 200 mg (as fumarate)

8580N *Quetiapine-Synthon, ZT* – **Quetiapine**, Tablet 300 mg (as fumarate)

8456C *STADA Quetiapine, TD* – **Quetiapine**, Tablet 25 mg (as fumarate)

8457D *STADA Quetiapine, TD* – **Quetiapine**, Tablet 100 mg (as fumarate)

8458E *STADA Quetiapine, TD* – **Quetiapine**, Tablet 200 mg (as fumarate)

8580N *STADA Quetiapine, TD* – **Quetiapine**, Tablet 300 mg (as fumarate)

9120B *APO-Ramipril, TX* – **Ramipril**, Capsule 1.25 mg

9120B *Chem mart Ramipril, CH* – **Ramipril**, Capsule 1.25 mg

9120B *Terry White Chemists Ramipril, TW* – **Ramipril**, Capsule 1.25 mg

9121C *APO-Ramipril, TX* – **Ramipril**, Capsule 2.5 mg

9121C *Chem mart Ramipril, CH* – **Ramipril**, Capsule 2.5 mg

9121C *Terry White Chemists Ramipril, TW* – **Ramipril**, Capsule 2.5 mg

9122D *APO-Ramipril, TX* – **Ramipril**, Capsule 5 mg

9122D *Chem mart Ramipril, CH* – **Ramipril**, Capsule 5 mg

9122D *Terry White Chemists Ramipril, TW* – **Ramipril**, Capsule 5 mg

1760P *Roxithromycin-PS, FZ* – **Roxithromycin**, Tablet 150 mg

5260W *Roxithromycin-PS, FZ* – **Roxithromycin**, Tablet 150 mg **(Dental)**

8016X *Roxithromycin-PS, FZ* – **Roxithromycin**, Tablet 300 mg

5261X *Roxithromycin-PS, FZ* – **Roxithromycin**, Tablet 300 mg **(Dental)**

2011W *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 10 mg

2012X *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 20 mg

8173E *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 40 mg

8313M *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 80 mg

9242K *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 10 mg

9243L *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 20 mg

9244M *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 40 mg

9245N *Simvastatin-DRLA, RZ* – **Simvastatin**, Tablet 80 mg

8144P *Sumagran Aspen 50, AS* – **Sumatriptan**, Tablet 50 mg (as succinate)

8378Y *Orion Temozolomide, ON* – **Temozolomide**, Capsule 5 mg

8379B *Orion Temozolomide, ON* – **Temozolomide**, Capsule 20 mg

8380C *Orion Temozolomide, ON* – **Temozolomide**, Capsule 100 mg

9362R *Orion Temozolomide, ON* – **Temozolomide**, Capsule 140 mg

8381D *Orion Temozolomide, ON* – **Temozolomide**, Capsule 250 mg

8819E *Orion Temozolomide, ON* – **Temozolomide**, Capsule 5 mg

8820F *Orion Temozolomide, ON* – **Temozolomide**, Capsule 20 mg

8821G *Orion Temozolomide, ON* – **Temozolomide**, Capsule 100 mg

9361Q *Orion Temozolomide, ON* – **Temozolomide**, Capsule 140 mg

Addition – Equivalence Indicator

1512N *Plaquenil, SW* – **Hydroxychloroquine Sulfate**, Tablet 200 mg

8243W *Xalatan, PF* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL

5552F *Xalatan, PF* – **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL **(Optometrical)**

8895E *Xalacom, PF* – **Latanoprost with Timolol Maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL

5553G *Xalacom, PF* – **Latanoprost with Timolol Maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL **(Optometrical)**

9151P *Sifrol, BY* – **Pramipexole Hydrochloride**, Tablet 125 micrograms

9152Q *Sifrol, BY* – **Pramipexole Hydrochloride**, Tablet 250 micrograms

9153R *Sifrol, BY* – **Pramipexole Hydrochloride**, Tablet 1 mg

Addition – Note

1382R **Ranibizumab**, Solution for intravitreal injection 2.3 mg in 0.23 mL *(Lucentis)*

Deletions

Deletion – Item

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

Deletion – Brand

3318P *Cephabell, BF* – **Cephalexin**, Capsule 500 mg **(Dental)**

3119E *Cephabell, BF* – **Cephalexin**, Capsule 500 mg

8220P *Citalobell, BF* – **Citalopram Hydrobromide**, Tablet 20 mg (base)

2449X *Mellihexal, SZ* – **Gliclazide**, Tablet 80 mg

8621R *Actonel Once-a-Week, SW* – **Risedronate Sodium**, Tablet 35 mg

8899J *Actonel Combi, SW* – **Risedronate Sodium and Calcium Carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)

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

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

Deletion – Equivalence Indicator

8899J *Acris Combi, AF* – **Risedronate Sodium and Calcium Carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)

Alterations

Alteration – Brand Name

From:

5484P *GA express, VF* – **Amino Acid Formula with Vitamins and Minerals without Lysine and low in Tryptophan**, Sachets 25 g, 30

To:

5484P *GA express 15, VF*– **Amino Acid Formula with Vitamins and Minerals without Lysine and low in Tryptophan**, Sachets 25 g, 30

From:

8744F *HCU express, VF* – **Amino Acid Formula with Vitamins and Minerals without Methionine**, Sachets 25 g, 30

To:

8744F *HCU express 15, VF* – **Amino Acid Formula with Vitamins and Minerals without Methionine**, Sachets 25 g, 30

From:

3443F *MMA/PA express, VF* – **Amino Acid Formula with Vitamins and Minerals without Methionine, Threonine and Valine and low in Isoleucine**, Sachets 25 g, 30

To:

3443F *MMA/PA express 15, VF* – **Amino Acid Formula with Vitamins and Minerals without Methionine, Threonine and Valine and low in Isoleucine**, Sachets 25 g, 30

From:

8591E *PKU express, VF* – **Amino Acid Formula with Vitamins and Minerals without Phenylalanine**, Sachets 25 g, 30

To:

8591E *PKU express 15, VF* – **Amino Acid Formula with Vitamins and Minerals without Phenylalanine**, Sachets 25 g, 30

From:

8667E *TYR express, VF* –**Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine**, Sachets 25 g, 30

To:

8667E *TYR express 15, VF* – **Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine**, Sachets 25 g, 30

From:

8632H *MSUD express, VF* – **Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine**, Sachets 25 g, 30

To:

8632H *MSUD express 15, VF* – **Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine**, Sachets 25 g, 30

From:

1784X *Max Pharma Pty Ltd, XF* – **Ceftriaxone**, Powder for injection 1 g

To:

1784X *Max Pharma Ceftriaxone, GQ* – **Ceftriaxone**, Powder for injection 1 g

Alteration – Maximum Quantity

		From:	*To:*
8349K	**Morphine Sulfate**, Capsule 10 mg (containing sustained release pellets) *(Kapanol)*	20	28
2839K	**Morphine Sulfate**, Capsule 20 mg (containing sustained release pellets) *(Kapanol)*	20	28
2840L	**Morphine Sulfate**, Capsule 50 mg (containing sustained release pellets) *(Kapanol)*	20	28
2841M	**Morphine Sulfate**, Capsule 100 mg (containing sustained release pellets) *(Kapanol)*	20	28

Alteration – Restriction

5457F **Denosumab**, Injection 60 mg in 1 mL pre-filled syringe *(Prolia)*

Alteration – Manufacturer's Code

		From:	*To:*
5281Y	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
5282B	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
5283C	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
5284D	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
8737W	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
8741C	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
8961P	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe, 6	AB	VE
8962Q	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen, 6	AB	VE
8963R	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
8964T	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
8965W	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
8966X	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9033K	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9034L	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9077R	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9078T	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9099X	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9100Y	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9101B	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9102C	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9103D	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9104E	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9186L	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe, 6	AB	VE
9187M	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen, 6	AB	VE
9188N	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9189P	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9190Q	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9191R	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9425C	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9426D	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
9427E	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe	AB	VE
9428F	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen	AB	VE
8511Y	*Alendrobell 70mg, GQ* – **Alendronate Sodium**, Tablet equivalent to 70 mg alendronic acid	BF	GQ
1788D	*Max Pharma Ceftriaxone, GQ* – **Ceftriaxone**, Powder for injection 1 g	XF	GQ
1209P	*Ciprofloxacin-BW, GQ* – **Ciprofloxacin**, Tablet 500 mg	BF	GQ
1210Q	*Ciprofloxacin-BW, GQ* – **Ciprofloxacin**, Tablet 750 mg	BF	GQ
1313D	*Diltahexal CD, HX* – **Diltiazem Hydrochloride**, Capsule 240 mg (controlled delivery)	SZ	HX
8480H	*Diltahexal CD, HX* – **Diltiazem Hydrochloride**, Capsule 360 mg (controlled delivery)	SZ	HX

		From:	*To:*
8875D	*Lucrin Depot 7.5mg PDS, VE* – **Leuprorelin Acetate**, I.M. injection (modified release), powder for injection 7.5 mg with diluent in pre-filled dual-chamber syringe	AB	VE
8876E	*Lucrin Depot 3 Month PDS, VE* – **Leuprorelin Acetate**, I.M. injection (modified release), powder for injection 22.5 mg with diluent in pre-filled dual-chamber syringe	AB	VE
8877F	*Lucrin Depot 4 Month PDS, VE* – **Leuprorelin Acetate**, I.M. injection (modified release), powder for injection 30 mg with diluent in pre-filled dual-chamber syringe	AB	VE
8970D	*Duodopa, VE* – **Levodopa with Carbidopa**, Intestinal gel 20 mg-5 mg per mL, 100 mL	AB	VE
8561N	*Meloxibell, GQ* – **Meloxicam**, Tablet 7.5 mg	BF	GQ
8562P	*Meloxibell, GQ* – **Meloxicam**, Tablet 15 mg	BF	GQ

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

2008Q **Mannitol**, Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers *(bronchitol)***(Private)**

2015C **Mannitol**, Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers *(bronchitol)***(Public)**

Addition – Brand

6193Y *Lamivudine RBX, RA* – **Lamivudine**, Tablet 150 mg **(Private)**

5772T *Lamivudine RBX, RA* – **Lamivudine**, Tablet 150 mg **(Public)**

6435Q *Lamivudine RBX, RA* – **Lamivudine**, Tablet 300 mg **(Private)**

5774X *Lamivudine RBX, RA* – **Lamivudine**, Tablet 300 mg **(Public)**

Addition – Equivalence Indicator

6193Y *3TC, VI* – **Lamivudine**, Tablet 150 mg **(Private)**

5772T *3TC, VI* – **Lamivudine**, Tablet 150 mg **(Public)**

6435Q *3TC, VI* – **Lamivudine**, Tablet 300 mg **(Private)**

5774X *3TC, VI* – **Lamivudine**, Tablet 300 mg **(Public)**

Addition – Note

6120D **Dornase Alfa**, Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL *(Pulmozyme)***(Private)**

5704F **Dornase Alfa**, Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL *(Pulmozyme)***(Public)**

Deletions

Deletion – Item

9656F **Tipranavir**, Oral liquid 100 mg per mL, 95 mL *(Aptivus)***(Public)**

9676G **Tipranavir**, Oral liquid 100 mg per mL, 95 mL *(Aptivus)***(Private)**

Alterations

Alteration – Manufacturer's Code

		From	*To*
9661L	*Humira, VE* – **Adalimumab**, Injection 20 mg in 0.4 mL pre-filled syringe **(Public)**	AB	VE
9662M	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe **(Public)**	AB	VE
9663N	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen **(Public)**	AB	VE

		From	*To*
9678J	*Humira, VE* – **Adalimumab**, Injection 20 mg in 0.4 mL pre-filled syringe **(Private)**	AB	VE
9679K	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe **(Private)**	AB	VE
9680L	*Humira, VE* – **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen **(Private)**	AB	VE
9743T	*Duodopa, VE* – **Levodopa with Carbidopa**, Intestinal gel 20 mg-5 mg per mL, 100 mL **(Public)**	AB	VE
9744W	*Duodopa, VE* – **Levodopa with Carbidopa**, Intestinal gel 20 mg-5 mg per mL, 100 mL **(Private)**	AB	VE
9633B	*Kaletra, VE* – **Lopinavir with Ritonavir**, Tablet 100 mg-25 mg **(Private)**	AB	VE
5790R	*Kaletra, VE* – **Lopinavir with Ritonavir**, Tablet 100 mg-25 mg **(Public)**	AB	VE
6495W	*Kaletra, VE* – **Lopinavir with Ritonavir**, Tablet 200 mg-50 mg **(Private)**	AB	VE
5791T	*Kaletra, VE* – **Lopinavir with Ritonavir**, Tablet 200 mg-50 mg **(Public)**	AB	VE
6341R	*Kaletra, VE* – **Lopinavir with Ritonavir**, Oral liquid 400 mg-100 mg per 5 mL, 60 mL **(Private)**	AB	VE
5789Q	*Kaletra, VE* – **Lopinavir with Ritonavir**, Oral liquid 400 mg-100 mg per 5 mL, 60 mL **(Public)**	AB	VE
6227R	*Octreotide MaxRx, GQ* – **Octreotide**, Injection 50 micrograms (as acetate) in 1 mL **(Private)**	XF	GQ
9508K	*Octreotide MaxRx, GQ* – **Octreotide**, Injection 50 micrograms (as acetate) in 1 mL **(Public)**	XF	GQ
6228T	*Octreotide MaxRx, GQ* – **Octreotide**, Injection 100 micrograms (as acetate) in 1 mL **(Private)**	XF	GQ
9509L	*Octreotide MaxRx, GQ* – **Octreotide**, Injection 100 micrograms (as acetate) in 1 mL **(Public)**	XF	GQ
6229W	*Octreotide MaxRx, GQ* – **Octreotide**, Injection 500 micrograms (as acetate) in 1 mL **(Private)**	XF	GQ
9510M	*Octreotide MaxRx, GQ* – **Octreotide**, Injection 500 micrograms (as acetate) in 1 mL **(Public)**	XF	GQ
9677H	*Norvir, VE* – **Ritonavir**, Tablet 100 mg **(Private)**	AB	VE
9660K	*Norvir, VE* – **Ritonavir**, Tablet 100 mg **(Public)**	AB	VE
6494T	*Norvir, VE* – **Ritonavir**, Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL **(Private)**	AB	VE
9542F	*Norvir, VE* – **Ritonavir**, Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL **(Public)**	AB	VE

REPATRIATION PHARMACEUTICAL BENEFITS

Alterations

Alteration – Brand Name

From:

4422R *Metamucil Regular, PY* – **Psyllium Hydrophilic Mucilloid,** Oral powder (non-flavoured) 336 g

To:

4422R *Metamucil Natural Granular, PY* – **Psyllium Hydrophilic Mucilloid,** Oral powder (non-flavoured) 336 g

From:

4419N *Metamucil Smooth Texture Orange, PY* – **Psyllium Hydrophilic Mucilloid,** Oral powder (orange-flavoured, sugar-free) 283 g

To:

4419N *Metamucil Orange Smooth, PY* – **Psyllium Hydrophilic Mucilloid,** Oral powder (orange-flavoured, sugar-free) 283 g

Alteration – Item Description

From:

4948K **Dressing—hydroactive (debridement)**, Dressings 5.5 cm, 8 *(TenderWet Active Cavity)*

To:

4948K **Dressing—hydroactive (debridement)**, Dressings 5.5 cm, 10 *(TenderWet Active Cavity)*

From:

4949L **Dressing—hydroactive (debridement)**, Dressings 4 cm, 8 *(TenderWet 24 Active)*

To:

4949L **Dressing—hydroactive (debridement)**, Dressings 4 cm, 10 *(TenderWet 24 Active)*

From:

4950M **Dressing—hydroactive (debridement)**, Dressings 7.5 cm x 7.5 cm, 8 *(TenderWet 24 Active)*

To:

4950M **Dressing—hydroactive (debridement)**, Dressings 7.5 cm x 7.5 cm, 10 *(TenderWet 24 Active)*

Advance Notices

Advance Notices – Deletion of Item

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

9163G **Calcipotriol**, Scalp solution 50 micrograms per mL (0.005%), 30 mL *(Daivonex)*

2920Q **Disodium Etidronate**, Tablet 200 mg *(Didronel)*

8056B **Disodium Etidronate and Calcium Carbonate**, Pack containing 28 tablets disodium etidronate 200 mg and 76 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) *(Didrocal)*

9193W **Glucose Indicator—blood**, Test strips, 25 *(On-Call Plus)*

9256E **Glucose Indicator—blood**, Test strips, 25 *(On-Call Plus)*

1253Y **±ŜŊl·ǇI·Yʎf lèŘŊ2ŎKf2ŊʎŘŜ**, Tablet 160 mg *(Isoptin)*

Deletion requested by manufacturer —

2530E **Lincomycin**, Injection 600 mg in 2 mL *(Lincocin)*

5144R **Lincomycin**, Injection 600 mg in 2 mL *(Lincocin)* (**Dental)**

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

2244D **Amino Acids—synthetic, Formula**, Compound powder 400 g *(Neocate Advance Tropical Flavour)*

2553J **Amino Acids—synthetic, Formula**, Compound powder 400 g *(Neocate Advance Tropical Flavour)*

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

2820K **Betamethasone Valerate**, Ointment 200 micrograms (base) per g (0.02%), 100 g *(Celestone-M, Antroquoril)*

1060T **Verapamil Hydrochloride**, Injection 5 mg in 2 mL *(Isoptin)*

3494X **Verapamil Hydrochloride**, Injection 5 mg in 2 mL *(Isoptin)***(Emergency Drug Supply)**

Advance Notices – Deletion of Brand

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

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

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

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

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

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

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

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

1278G *Timoptol, FR* – **Timolol Maleate**, Eye drops 2.5 mg (base) per mL (0.25%), 5 mL

5547Y *Timoptol, FR* – **Timolol Maleate**, Eye drops 2.5 mg (base) per mL (0.25%), 5 mL **(Optometrical)**

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

2488Y *Pepcidine, MK* – **Famotidine**, Tablet 40 mg

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

8316Q *Maxipime, BQ* – **Cefepime**, Powder for injection 2 g (as hydrochloride) (solvent required)

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	
	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE							
	Restricted benefit							
	Methylmalonic acidaemia;							
	Propionic acidaemia.							
1923F *NP*	Oral liquid 130 mL, 30	4	5	..	*3098.48	35.40	MMA/PA cooler	VF
	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE							
	Restricted benefit							
	Phenylketonuria.							
1909L *NP*	Sachets 34 g, 30	4	5	..	*2054.12	35.40	PKU express 20	VF
	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE							
	Restricted benefit							
	Maple syrup urine disease.							
1914R *NP*	Sachets 34 g, 30	4	5	..	*4094.24	35.40	MSUD express 20	VF
	AURANOFIN							
	Caution							
	Regular blood and urine checks are essential.							
2022K *NP*	Capsule 3 mg	60	5	..	779.09	35.40	Ridaura	BZ
	CEFUROXIME AXETIL							
5499K	Powder for oral suspension 125 mg (base) per 5 mL, 70 mL	‡1	1	..	#19.54	20.99	Zinnat	GK
	DENOSUMAB							
	Authority required (STREAMLINED)							
	4054							
	Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a woman 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;							
	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	..	..	298.79	35.40	Prolia	AN
	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).							

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

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 UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of etanercept for patients under 18 years with severe chronic plaque psoriasis.

Applications under this restriction will be limited to provide patients with a maximum of 24 weeks of therapy. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment.

A patient may fail to respond to PBS-subsidised etanercept twice under this restriction. Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for 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 for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:
(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Assessment of response to treatment.

When prescribing treatment with etanercept, 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 12 weeks 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 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.

A prescription for a further 8 weeks of treatment should be submitted with the PASI assessment. This will complete 24 weeks of treatment for eligible patients.

(4) 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 etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted 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 gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The PASI assessments must not be older than 1 month at the time of application.

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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 treatment [Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist of a patient under 18 years who:
(a) has severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) has not received any prior PBS-subsidised treatment with etanercept for this condition; and
(c) whose parent or authorised guardian has signed a patient acknowledgement; and
(d) has failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 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 or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or
(iii) 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 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 in Patients Less Than 18 Years 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 parent or authorised guardian signed patient and prescriber acknowledgements.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance of treatment, a further 8 weeks treatment, will be authorised if the submitted PASI assessment shows an adequate demonstrated response to treatment.

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 a further 8 weeks of treatment under this restriction, 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 initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

Authority required

Re-Treatment [Whole body (Received prior etanercept under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for a patient under 18 years who has:
(a) a documented history of severe chronic plaque psoriasis; and
(b) received prior PBS-subsidised treatment with etanercept for this condition; and
(c) not failed PBS-subsidised therapy with etanercept for the treatment of this condition more than once 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 in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form [may be

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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 etanercept treatment, including date.

A total maximum of 24 weeks of treatment with etanercept will be authorised under this restriction. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance of treatment, a further 8 weeks treatment, will be authorised if the submitted PASI assessment shows an adequate demonstrated response to treatment.

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 a further 8 weeks of treatment under this restriction, 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 initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Authority required

Initial treatment [Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist of a patient under 18 years who:
(a) has 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) has not received any prior PBS-subsidised treatment with etanercept for this condition; and
(c) whose parent or authorised guardian has signed a patient acknowledgement; and
(d) has failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 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 or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or
(iii) 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 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 in Patients Less Than 18 Years 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 parent or authorised guardian signed patient and prescriber acknowledgements.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance of treatment, a further 8 weeks treatment, will be authorised if the submitted PASI assessment shows an adequate demonstrated response to treatment.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a

GENERAL PHARMACEUTICAL BENEFITS

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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 a further 8 weeks of treatment under this restriction, 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 initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

Authority required

Re-Treatment [Face, hand, foot (Received prior etanercept under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for a patient under 18 years who has:
(a) a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) received prior PBS-subsidised treatment with etanercept for this condition; and
(c) not failed PBS-subsidised therapy with etanercept for the treatment of this condition more than once 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 in Patients Less Than 18 Years 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 etanercept treatment, including date.

A total maximum of 24 weeks of treatment with etanercept will be authorised under this restriction. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance of treatment, a further 8 weeks treatment, will be authorised if the submitted PASI assessment shows an adequate demonstrated response to treatment.

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 a further 8 weeks of treatment under this restriction, 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 initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note

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

Note

Special Pricing Arrangements apply.

1954W	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1829.10	35.40	Enbrel	PF
1963H	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1774.47	35.40	Enbrel	PF
1964J	Injection 50 mg in 1 mL single use auto-injector, 4	1	3	..	1774.47	35.40	Enbrel	PF

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	
	ICATIBANT							
	Authority required							
	Initial supply for anticipated emergency treatment of an acute attack of hereditary angioedema in a patient with confirmed diagnosis of C1-esterase inhibitor deficiency who has been assessed to be at significant risk of an acute attack of hereditary angioedema by or in consultation with a clinical immunologist, respiratory physician, specialist allergist or general physician experienced in the management of patients with hereditary angioedema.							
	The name of the specialist consulted must be provided at the time of application for initial supply.							
	The name of the Approved Pathology Authority and date of the diagnosing pathology test must be included in the authority application;							
	Continuing supply for anticipated emergency treatment of an acute attack of hereditary angioedema, where the patient has previously been issued with an authority prescription for this drug.							
	Note							
	Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)							
1976B	Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe	1	1	..	2571.46	35.40	Firazyr	ZI
	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).							
	Note							
	Special Pricing Arrangements apply.							
1382R	Solution for intravitreal injection 2.3 mg in 0.23 mL	1	2	..	1976.46	35.40	Lucentis	NV
	RASAGILINE							
	Authority required (STREAMLINED)							
	4053							
	Parkinson disease.							

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	
	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.							
1952R *NP*	Tablet 1 mg (as mesilate)	30	5	..	121.69	35.40	Azilect	LU
	TICAGRELOR **Authority required (STREAMLINED)** ***3879*** Treatment of acute coronary syndrome (myocardial infarction or unstable angina) 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.							
1418P *NP*	Tablet 90 mg	56	5	..	149.10	35.40	Brilinta	AP
	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 Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.							
1938B *NP*	Compound powder 400 g	8	5	..	*442.92	35.40	Lipistart	VF

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	
	CEFUROXIME AXETIL							
2002J	Powder for oral suspension 125 mg (base) per 5 mL, 70 mL	‡1	..	..	#19.54	20.99	Zinnat	GK

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

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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

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

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	

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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

5704F	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	60	5	..	*2360.00	Pulmozyme	RO

MANNITOL

Authority required (STREAMLINED)

4063

Treatment of cystic fibrosis in a patient who satisfies all of the following criteria:
(1) Prior to mannitol therapy, the patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved PI mannitol initiation dose assessment. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol;
(2) Is 6 years of age or older;
(3) Has a FEV1 greater than 30% predicted for age, gender and height;
(4) Is intolerant or inadequately responsive to dornase alfa;
(5) Has 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);
(6) Is participating in a 4 week trial, as detailed below, or has achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to mannitol 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 mannitol therapy 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 mannitol 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 mannitol at a dose of 400 mg twice 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 mannitol treatment) are eligible for continued subsidy under the HSD program at a dose of 400mg twice daily;
(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 400 mg twice 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 mannitol powder for inhalation treatment is continuing to produce worthwhile benefits. (Mannitol 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 mannitol 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

Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

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) ***4064*** Grandfather — for patients who initiated mannitol treatment prior to 1 August 2012 Continuation of treatment of cystic fibrosis in a patient 6 years of age or older, who initiated treatment with mannitol prior to 1 August 2012 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, documents agreement that mannitol treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. **Note** Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa. It is highly desirable that all patients be included in the national cystic fibrosis patient database.						
2015C	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	4	5	..	*1736.00	bronchitol	XA

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

DORNASE ALFA

Authority required

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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

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

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

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 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

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

6120D	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	60	5	..	*2406.52	Pulmozyme	RO

MANNITOL

Authority required

Treatment of cystic fibrosis in a patient who satisfies all of the following criteria:
(1) Prior to mannitol therapy, the patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved PI mannitol initiation dose assessment. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol;
(2) Is 6 years of age or older;
(3) Has a FEV1 greater than 30% predicted for age, gender and height;
(4) Is intolerant or inadequately responsive to dornase alfa;
(5) Has 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);
(6) Is participating in a 4 week trial, as detailed below, or has achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to mannitol 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 mannitol therapy 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 mannitol 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 mannitol at a dose of 400 mg twice 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 mannitol treatment) are eligible for continued subsidy under the HSD program at a dose of 400mg twice daily;
(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 400 mg twice 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 mannitol powder for inhalation treatment is continuing to produce worthwhile benefits. (Mannitol 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 mannitol 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

Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required

Grandfather — for patients who initiated mannitol treatment prior to 1 August 2012

Continuation of treatment of cystic fibrosis in a patient 6 years of age or older, who initiated treatment with mannitol prior to 1 August 2012 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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	fibrosis team, documents agreement that mannitol treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. **Note** Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa. It is highly desirable that all patients be included in the national cystic fibrosis patient database.						
2008Q	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	4	5	..	*1782.52	bronchitol	XA