



Australian Government

Department of Health

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 January 2015

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 January 2015. 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 January 2015 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.76
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.80
	Allowable additional patient charge*	\$4.27
Additional Fees (for safety net prices):	Ready-prepared	\$1.15
	Extemporaneously-prepared	\$1.50
Patient Co-payments:	General	\$37.70
	Concessional	\$6.10
Safety Net Thresholds:	General	\$1453.90
	Concessional	\$366.00
Safety Net Card Issue Fee:		\$9.47

* 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

General Pharmaceutical Benefits

Additions

Addition – Item

10206E	EMPAGLIFLOZIN , empagliflozin 10 mg tablet, 30 (<i>Jardiance</i>)
10202Y	EMPAGLIFLOZIN , empagliflozin 25 mg tablet, 30 (<i>Jardiance</i>)
10203B	OESTRADIOL , oestradiol 10 microgram pessary: modified release, 18 (<i>Vagifem Low</i>)
10201X	ROSUVASTATIN (&) EZETIMIBE , rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack (<i>Rosuzet Composite Pack</i>)
10204C	ROSUVASTATIN (&) EZETIMIBE , rosuvastatin 5 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack (<i>Rosuzet Composite Pack</i>)
10207F	ROSUVASTATIN (&) EZETIMIBE , rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack (<i>Rosuzet Composite Pack</i>)
10208G	ROSUVASTATIN (&) EZETIMIBE , rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack (<i>Rosuzet Composite Pack</i>)
10205D	TESTOSTERONE UNDECANOATE , testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL vial (<i>Reandron 1000</i>)

Addition – Brand

2751T	<i>Pharmacor Amlodipine, CR</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
2752W	<i>Pharmacor Amlodipine, CR</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
8600P	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
8600P	<i>Esomeprazole Apotex, TX</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
8886Q	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
8886Q	<i>Esomeprazole Apotex, TX</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
3401B	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
3401B	<i>Esomeprazole Apotex, TX</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
8601Q	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
8601Q	<i>Esomeprazole Apotex, TX</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
1394J	<i>Eleanor 150/30 ED, EA</i> – ETHINYLOESTRADIOL + LEVONORGESTREL , ethinyloestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]
8814X	<i>APO-Osteo Paracetamol 665 mg, TX</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
8814X	<i>Blooms the Chemist Osteo Pain Relief Paracetamol 665 mg, IB</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
8814X	<i>Chem mart Pharmacy Osteo Relief Paracetamol 665 mg, CH</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
8814X	<i>Terry White Chemists Osteo Relief Paracetamol 665 mg, TW</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
9151P	<i>Pramipexole GH, GQ</i> – PRAMIPEXOLE , pramipexole hydrochloride monohydrate 125 microgram tablet, 30
9152Q	<i>Pramipexole GH, GQ</i> – PRAMIPEXOLE , pramipexole hydrochloride monohydrate 250 microgram tablet, 100
9153R	<i>Pramipexole GH, GQ</i> – PRAMIPEXOLE , pramipexole hydrochloride monohydrate 1 mg tablet, 100
8787L	<i>Risperidone Actavis 0.5, UA</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
8869T	<i>Risperidone Actavis 0.5, UA</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
3169T	<i>Risperidone Actavis 1, UA</i> – RISPERIDONE , risperidone 1 mg tablet, 60
8789N	<i>Risperidone Actavis 1, UA</i> – RISPERIDONE , risperidone 1 mg tablet, 60
2285G	<i>Terbinafine AN, EA</i> – TERBINAFINE , terbinafine 250 mg tablet, 42
2804N	<i>Terbinafine AN, EA</i> – TERBINAFINE , terbinafine 250 mg tablet, 42

Deletions

Deletion – Item

2260Y	SODIUM CHLORIDE , sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag (<i>Baxter Healthcare Pty Ltd</i>)
5213J	SODIUM CHLORIDE , sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag (<i>Baxter Healthcare Pty Ltd</i>) (Dental)
2279Y	SODIUM CHLORIDE + GLUCOSE , sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag (<i>Baxter Healthcare Pty Ltd</i>)
5215L	SODIUM CHLORIDE + GLUCOSE , sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag (<i>Baxter Healthcare Pty Ltd</i>) (Dental)
2278X	SODIUM CHLORIDE + GLUCOSE , sodium chloride 0.45% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag (<i>Baxter Healthcare Pty Ltd</i>)
5216M	SODIUM CHLORIDE + GLUCOSE , sodium chloride 0.45% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag (<i>Baxter Healthcare Pty Ltd</i>) (Dental)
2266G	SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE , sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, 1 x 1000 mL bag (<i>Baxter Healthcare Pty Ltd</i>)

Deletion – Brand

2730Q	<i>Terry White Chemists Baclofen, TW</i> – BACLOFEN , baclofen 25 mg tablet, 100
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1127H	<i>Cromolux, AE</i> – CROMOGLYCATE , cromoglycate sodium 2% eye drops, 10 mL
5529B	<i>Cromolux, AE</i> – CROMOGLYCATE , cromoglycate sodium 2% eye drops, 10 mL (Optometrical)
1695F	<i>Nifehexal, SZ</i> – NIFEDIPINE , nifedipine 20 mg tablet, 60
8363E	<i>Raloxifene AN, EA</i> – RALOXIFENE , raloxifene hydrochloride 60 mg tablet, 28
8973G	<i>Risedronate Winthrop EC Combi, WA</i> – RISEDRONATE (&) CALCIUM CARBONATE , RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1
8974H	<i>Risedronate Winthrop EC Combi D, WA</i> – RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL , RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

Deletion – Equivalence Indicator

1127H	<i>Opticrom, SW</i> – CROMOGLYCATE , cromoglycate sodium 2% eye drops, 10 mL
5529B	<i>Opticrom, SW</i> – CROMOGLYCATE , cromoglycate sodium 2% eye drops, 10 mL (Optometrical)
8973G	<i>Actonel EC Combi, UA</i> – RISEDRONATE (&) CALCIUM CARBONATE , RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1
8974H	<i>Actonel EC Combi D, UA</i> – RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL , RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

Alterations

Alteration – Brand Name

<i>From</i>	
2977Q	<i>Aspen Ampicyn, AF</i> – AMPICILLIN , ampicillin 1 g injection, 5 x 1 g vials
<i>To</i>	
2977Q	<i>Ampicyn, AF</i> – AMPICILLIN , ampicillin 1 g injection, 5 x 1 g vials
<i>From</i>	
3314K	<i>Aspen Ampicyn, AF</i> – AMPICILLIN , ampicillin 1 g injection, 5 x 1 g vials (Dental)
<i>To</i>	
3314K	<i>Ampicyn, AF</i> – AMPICILLIN , ampicillin 1 g injection, 5 x 1 g vials (Dental)

Alteration – Restriction Level

1166J	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 30 (<i>Dibenzyline</i>)	<i>From</i>	<i>To</i>
1862B	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 100 (<i>Dibenzyline</i>)	restricted	authority-required
9286R	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 100 (<i>Dibenzyline</i>)	restricted	authority-required

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
9192T	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL	AB	GO
8318T	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg tablet, 14	AB	GO
8397Y	<i>Teveten</i> – EPROSARTAN , eprosartan 400 mg tablet, 28	AB	GO
8951D	<i>Teveten</i> – EPROSARTAN , eprosartan 400 mg tablet, 28	AB	GO
5491B	<i>Teveten</i> – EPROSARTAN , eprosartan 600 mg tablet, 28	AB	GO
8447N	<i>Teveten</i> – EPROSARTAN , eprosartan 600 mg tablet, 28	AB	GO
8624X	<i>Teveten Plus 600/12.5</i> – EPROSARTAN + HYDROCHLOROTHIAZIDE , eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28	AB	GO
9022W	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60	AB	GO
9246P	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60	AB	GO
9023X	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30	AB	GO
9247Q	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30	AB	GO
8512B	<i>Luvox</i> – FLUVOXAMINE , fluvoxamine maleate 50 mg tablet, 30	AB	GO
8174F	<i>Luvox</i> – FLUVOXAMINE , fluvoxamine maleate 100 mg tablet, 30	AB	GO
8759B	<i>CareSens</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 50	LB	PB
9278H	<i>CareSens</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 50	LB	PB
3406G	<i>CareSens N</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 50	LB	PB
3407H	<i>CareSens N</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 50	LB	PB
3190X	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	AB	GO
3192B	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	AB	GO
5123P	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30 (Dental)	AB	GO
5124Q	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30 (Dental)	AB	GO
8534E	<i>Zanidip</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28	AB	GO
8679T	<i>Zanidip</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28	AB	GO
9144G	<i>Zan-Extra 10/10</i> – LERCANIDIPINE + ENALAPRIL , lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg	AB	GO

	tablet, 28		
9145H	Zan-Extra 10/20 – LERCANIDIPINE + ENALAPRIL , lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28	AB	GO
9019Q	Physiotens – MOXONIDINE , moxonidine 200 microgram tablet, 30	AB	GO
9020R	Physiotens – MOXONIDINE , moxonidine 400 microgram tablet, 30	AB	GO
8274L	Zumenon – OESTRADIOL , oestradiol 2 mg tablet, 56	AB	GO
10146B	Femoston 1/10 – OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE , oestradiol 1 mg tablet [14] (&) oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 28	AB	GO
8244X	Femoston 2/10 – OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE , oestradiol 2 mg tablet [14] (&) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 28	AB	GO
10142T	Femoston-Conti – OESTRADIOL + DYDROGESTERONE , oestradiol 1 mg + dydrogesterone 5 mg tablet, 28	AB	GO
8020D	Creon 10,000 – PANCREATIC EXTRACT , pancreatic extract 10 000 international units capsule: modified release, 100 capsules	AB	GO
9226N	Creon 10,000 – PANCREATIC EXTRACT , pancreatic extract 10 000 international units capsule: modified release, 100 capsules	AB	GO
8021E	Creon 25,000 – PANCREATIC EXTRACT , pancreatic extract 25 000 international units capsule: modified release, 100 capsules	AB	GO
9227P	Creon 25,000 – PANCREATIC EXTRACT , pancreatic extract 25 000 international units capsule: modified release, 100 capsules	AB	GO
9412J	Creon 40,000 – PANCREATIC EXTRACT , pancreatic extract 40 000 international units capsule: modified release, 100 capsules	AB	GO
9413K	Creon 40,000 – PANCREATIC EXTRACT , pancreatic extract 40 000 international units capsule: modified release, 100 capsules	AB	GO
5453B	Creon Micro – PANCREATIC EXTRACT , pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g	AB	GO
5454C	Creon Micro – PANCREATIC EXTRACT , pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g	AB	GO
8481J	Actonel – RISEDRONATE , risedronate sodium 5 mg tablet, 28	SW	UA
8482K	Actonel – RISEDRONATE , risedronate sodium 30 mg tablet, 28	SW	UA
8972F	Actonel EC – RISEDRONATE , RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4	SW	UA
9391G	Actonel Once-a-Month – RISEDRONATE , risedronate sodium 150 mg tablet, 1	SW	UA
8973G	Actonel EC Combi – RISEDRONATE (&) CALCIUM CARBONATE , RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1	SW	UA
8974H	Actonel EC Combi D – RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL , RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1	SW	UA
2791X	Gopten – TRANDOLAPRIL , trandolapril 500 microgram capsule, 28	AB	GO
2792Y	Gopten – TRANDOLAPRIL , trandolapril 1 mg capsule, 28	AB	GO
2793B	Gopten – TRANDOLAPRIL , trandolapril 2 mg capsule, 28	AB	GO
8758Y	Gopten – TRANDOLAPRIL , trandolapril 4 mg capsule, 28	AB	GO
9387C	Tarka 2/180 – TRANDOLAPRIL + VERAPAMIL , trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28 tablets	AB	GO
2857J	Tarka 4/240 – TRANDOLAPRIL + VERAPAMIL , trandolapril 4 mg + verapamil hydrochloride 240 mg tablet: modified release, 28 tablets	AB	GO
1250T	Isoptin – VERAPAMIL , verapamil hydrochloride 80 mg tablet, 100	AB	GO
2208F	Cordilox 180 SR – VERAPAMIL , verapamil hydrochloride 180 mg tablet: modified release, 30 tablets	KN	GT
2208F	Isoptin 180 SR – VERAPAMIL , verapamil hydrochloride 180 mg tablet: modified release, 30 tablets	AB	GO
1241H	Cordilox SR – VERAPAMIL , verapamil hydrochloride 240 mg tablet: modified release, 30 tablets	KN	GT
1241H	Isoptin SR – VERAPAMIL , verapamil hydrochloride 240 mg tablet: modified release, 30 tablets	AB	GO

Changes to Restrictions

The following items have additions, deletions or alterations to restrictions and/or notes.

2751T	AMLODIPINE , amlodipine 5 mg tablet, 30 (<i>APO-Amlodipine, Amlodipine Sandoz, Amlodipine generichealth, Amlodipine-DRLA, Auro-Amlodipine 5, Chem mart Amlodipine, Nordip, Norvapine, Norvasc, Ozlodip, Pharmacor Amlodipine, Terry White Chemists Amlodipine</i>)
2752W	AMLODIPINE , amlodipine 10 mg tablet, 30 (<i>APO-Amlodipine, Amlodipine Sandoz, Amlodipine generichealth, Amlodipine-DRLA, Auro-Amlodipine 10, Chem mart Amlodipine, Nordip, Norvapine, Norvasc, Ozlodip, Pharmacor Amlodipine, Terry White Chemists Amlodipine</i>)
2873F	CANAGLIFLOZIN , canagliflozin 100 mg tablet, 30 (<i>Invokana</i>)
2987F	CANAGLIFLOZIN , canagliflozin 300 mg tablet, 30 (<i>Invokana</i>)
8637N	ETANERCEPT , etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
8638P	ETANERCEPT , etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9089J	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
9090K	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
9459W	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)

9460X **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
1166J **PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 30 (*Dibenyline*)
1862B **PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 100 (*Dibenyline*)
9286R **PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 100 (*Dibenzyline*)
10087X **SAPROPTERIN**, sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets (*Kuvan*)

Advance Notices

1 February 2015

Deletion – Item

2095G **TICLOPIDINE**, ticlopidine hydrochloride 250 mg tablet, 60 (*Tilodene*)

Deletion – Brand

2360F **CHLORAMPHENICOL**, chloramphenicol 0.5% eye drops, 10 mL (*Chloromycetin*)
5055C **CHLORAMPHENICOL**, chloramphenicol 0.5% eye drops, 10 mL (*Chloromycetin*)
5512D **CHLORAMPHENICOL**, chloramphenicol 0.5% eye drops, 10 mL (*Chloromycetin*)

1 March 2015

Deletion – Item

8849R **ESCITALOPRAM**, escitalopram 10 mg/mL oral liquid, 28 mL (*Lexapro*)

1 May 2015

Deletion – Item

9004X **TESTOSTERONE UNDECANOATE**, testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule (*Reandron 1000*)

Palliative Care

Additions

Addition – Brand

5343F	<i>APO-Osteo Paracetamol 665 mg, TX</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5344G	<i>APO-Osteo Paracetamol 665 mg, TX</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5343F	<i>Blooms the Chemist Osteo Pain Relief Paracetamol 665 mg, IB</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5344G	<i>Blooms the Chemist Osteo Pain Relief Paracetamol 665 mg, IB</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5343F	<i>Chem mart Pharmacy Osteo Relief Paracetamol 665 mg, CH</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5344G	<i>Chem mart Pharmacy Osteo Relief Paracetamol 665 mg, CH</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5343F	<i>Terry White Chemists Osteo Relief Paracetamol 665 mg, TW</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5344G	<i>Terry White Chemists Osteo Relief Paracetamol 665 mg, TW</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
5368M	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	AB	GO
5370P	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	AB	GO

Advance Notices

1 February 2015

Deletion – Item

5333Q	CARMELLOSE SODIUM , carmellose sodium 10 mg/mL oral spray, 25 mL (<i>Aquae</i>)
5334R	CARMELLOSE SODIUM , carmellose sodium 10 mg/mL oral spray, 100 mL (<i>Aquae</i>)
5335T	CARMELLOSE SODIUM , carmellose sodium 10 mg/mL oral spray, 25 mL (<i>Aquae</i>)
5336W	CARMELLOSE SODIUM , carmellose sodium 10 mg/mL oral spray, 100 mL (<i>Aquae</i>)
5421H	HYPROMELLOSE , HYPROMELLOSE Oral gel 20 mg per g, 100 g, 1 (<i>Aquae Gel</i>)
5422J	HYPROMELLOSE , HYPROMELLOSE Oral gel 20 mg per g, 100 g, 1 (<i>Aquae Gel</i>)

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

9547L *SILDENAFIL-DRx, RZ* – **SILDENAFIL**, sildenafil 20 mg tablet, 90

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
5625C	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg tablet, 100	AB	GO
5624B	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 500 mg tablet, 100	AB	GO
9668W	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes	NV	SZ
9669X	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 2000 international units/mL injection, 6 x 1 mL syringes	NV	SZ
9670Y	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	NV	SZ
9587N	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes	NV	SZ
9589Q	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes	NV	SZ
9591T	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes	NV	SZ
9594Y	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes	NV	SZ
9596C	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 10 000 international units/mL injection, 6 x 1 mL syringes	NV	SZ

Advance Notices

1 February 2015

Deletion – Item

5620T *CIDOFOVIR*, **CIDOFOVIR**, cidofovir 375 mg/5 mL injection, 1 x 5 mL vial (Vistide)

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

9605M *SILDENAFIL-DRx, RZ* – **SILDENAFIL**, sildenafil 20 mg tablet, 90

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
6151R	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg tablet, 100	AB	GO
6152T	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 500 mg tablet, 100	AB	GO
9685R	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes	NV	SZ
9686T	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 2000 international units/mL injection, 6 x 1 mL syringes	NV	SZ
9687W	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	NV	SZ
9688X	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes	NV	SZ
9588P	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes	NV	SZ
9590R	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes	NV	SZ
9593X	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes	NV	SZ
9595B	<i>Novicrit</i> – EPOETIN LAMBDA , epoetin lambda 10 000 international units/mL injection, 6 x 1 mL syringes	NV	SZ

Advance Notices

1 February 2015

Deletion – Item

6247T *CIDOFOVIR*, cidofovir 375 mg/5 mL injection, 1 x 5 mL vial (Vistide)

Repatriation Pharmaceutical Benefits

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
4222F	<i>Efudix</i> – FLUOROURACIL , fluorouracil 5% (50 mg/g) cream, 20 g	VT	IA
4313B	<i>Claratyne</i> – LORATADINE , loratadine 10 mg tablet, 30	MK	BN
4378K	<i>Drixine</i> – OXYMETAZOLINE , oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 15 mL	MK	BN
4443W	<i>Actonel</i> – RISEDRONATE , risedronate sodium 5 mg tablet, 28	SW	UA
2191H	<i>Actonel EC</i> – RISEDRONATE , RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4	SW	UA
2220W	<i>Actonel EC Combi</i> – RISEDRONATE (&) CALCIUM CARBONATE , RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1	SW	UA
2254P	<i>Actonel EC Combi D</i> – RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL , RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1	SW	UA
4070F	<i>Flomaxtra</i> – TAMSULOSIN , tamsulosin hydrochloride 400 microgram tablet: modified release, 30	CS	LS
4481W	<i>Tinaderm</i> – TOLNAFTATE , tolnaftate 0.07% (700 microgram/g) spray, 100 g	MK	BN
4042R	<i>Urederm</i> – UREA , urea 10% (100 mg/g) cream, 100 g	VT	IA

Advance Notices

1 February 2015

Deletion – Item

4568K	CARMELLOSE SODIUM , carmellose sodium 10 mg/mL oral spray, 25 mL (<i>Aquae</i>)
4569L	CARMELLOSE SODIUM , carmellose sodium 10 mg/mL oral spray, 100 mL (<i>Aquae</i>)

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
AMLODIPINE							
2751T NP	amlodipine 5 mg tablet, 30	1	5	..	8.55	9.70	a APO-Amlodipine TX a Amlo 5 QA a Amlodipine Sandoz SZ a Amlodipine generichealth GQ a Amlodipine-DRLA RZ a Auro-Amlodipine 5 DO a Chem mart CH Amlodipine a Nordip AF a Norvapine GN a Ozlodip RA a Pharmacor CR Amlodipine a Terry White Chemists TW Amlodipine a Norvasc PF a APO-Amlodipine TX a Amlo 10 QA a Amlodipine Sandoz SZ a Amlodipine generichealth GQ a Amlodipine-DRLA RZ a Auro-Amlodipine 10 DO a Chem mart CH Amlodipine a Nordip AF a Norvapine GN a Ozlodip RA a Pharmacor CR Amlodipine a Terry White Chemists TW Amlodipine a Norvasc PF
2752W NP	amlodipine 10 mg tablet, 30	1	5	..	^B 5.54 14.09 .. 9.90	9.70 11.05	a Norvasc PF a APO-Amlodipine TX a Amlo 10 QA a Amlodipine Sandoz SZ a Amlodipine generichealth GQ a Amlodipine-DRLA RZ a Auro-Amlodipine 10 DO a Chem mart CH Amlodipine a Nordip AF a Norvapine GN a Ozlodip RA a Pharmacor CR Amlodipine a Terry White Chemists TW Amlodipine a Norvasc PF
				^B 8.19	18.09	11.05	a Norvasc PF

CANAGLIFLOZIN

Authority required

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

The condition must not be able to be adequately controlled by treatment with metformin and a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co- transporter 2 (SGLT2) inhibitor; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

GENERAL PHARMACEUTICAL BENEFITS

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Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

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

This drug is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

2873F NP	canagliflozin 100 mg tablet, 30	1	5	..	96.61	37.70	Invokana	JC
2987F NP	canagliflozin 300 mg tablet, 30	1	5	..	96.61	37.70	Invokana	JC

EMPAGLIFLOZIN

Authority required

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

The condition must not be able to be adequately controlled by treatment with metformin and a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co- transporter 2 (SGLT2) inhibitor; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

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

This drug is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
10202Y NP	empagliflozin 25 mg tablet, 30	1	5	..	96.38	37.70	Jardiance	BY
10206E NP	empagliflozin 10 mg tablet, 30	1	5	..	96.38	37.70	Jardiance	BY

ETANERCEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

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

GENERAL PHARMACEUTICAL BENEFITS

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time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted 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 within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug 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 treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and

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restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD

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supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

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Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug 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 treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) 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

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<p>Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.</p> <p>Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.</p> <p>A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.</p> <p>Abatacept patients:</p> <p>Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.</p> <p>In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.</p> <p>To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.</p> <p>PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.</p> <p>To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.</p> <p>(3) Baseline measurements to determine response.</p> <p>The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.</p> <p>To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.</p> <p>Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.</p> <p><u>Authority required</u> Severe active rheumatoid arthritis</p> <p>Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.</p> <p>Clinical criteria:</p> <p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,</p> <p>AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p> <p>Treatment criteria:</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Note</p> <p>Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:</p> <p>Department of Human Services Prior Written Approval of Complex Drugs</p>						

GENERAL PHARMACEUTICAL BENEFITS

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	Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
8637N	etanercept 25 mg injection [4 x 25 mg vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF
9089J	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9459W	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF

ETANERCEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) 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

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

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	<p>Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.</p> <p>Authority required Severe active rheumatoid arthritis</p> <p>Treatment Phase: Continuing Treatment – balance of supply</p> <p>Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.</p> <p>Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001</p>							
8638P	etanercept 25 mg injection [4 x 25 mg vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack	2	5	..	*1774.70	37.70	Enbrel	PF
9090K	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
9460X	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
OESTRADIOL								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
10203B NP	oestradiol 10 microgram pessary: modified release, 18	1	2	..	31.20	32.35	Vagifem Low	NO
PHENOXYBENZAMINE								
Authority required								
Phaeochromocytoma								
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.								
Authority required								
Neurogenic urinary retention								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1166J NP	phenoxybenzamine hydrochloride 10 mg capsule, 30	3	5	..	*205.24	37.70	Dibenylene	GH
1862B NP	phenoxybenzamine hydrochloride 10 mg capsule, 100	1	5	..	67.71	37.70	Dibenylene	GH
9286R NP	phenoxybenzamine hydrochloride 10 mg capsule, 100	1	5	..	6860.58	37.70	Dibenylene	BZ

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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ROSUVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

GENERAL PHARMACEUTICAL BENEFITS

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AND

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Note

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Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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.

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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.

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Note

Continuing Therapy Only:

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Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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Authority required (STREAMLINED)

GENERAL PHARMACEUTICAL BENEFITS

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	4097 Hypercholesterolaemia						
	Clinical criteria: Patient must have homozygous familial hypercholesterolaemia,						
	AND Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).						
	Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
10201X NP	rosuvastatin 20 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	#1	5	..	84.92	37.70	Rosuzet Composite Pack MK
10207F NP	rosuvastatin 40 mg tablet [30] (& ezetimibe 10 mg tablet [30 tablets], 1 pack	#1	5	..	90.75	37.70	Rosuzet Composite Pack MK
10208G NP	rosuvastatin 10 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	#1	5	..	80.97	37.70	Rosuzet Composite Pack MK

ROSUVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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Continuing Therapy Only:

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Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a

GENERAL PHARMACEUTICAL BENEFITS

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maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Note

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Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Note

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Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Note

Continuing Therapy Only:

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Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

GENERAL PHARMACEUTICAL BENEFITS

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

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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.

Authority required (STREAMLINED)**4097**

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia,

AND

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Note**Continuing Therapy Only:**

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

Authority required (STREAMLINED)**4147**

Hypercholesterolaemia

Clinical criteria:

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),

AND

Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Note**Continuing Therapy Only:**

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

10204C NP	rosuvastatin 5 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack	#1	5	..	77.85	37.70	Rosuzet Composite Pack	MK
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SAPROPTERIN**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Continuing

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Clinical criteria:								
Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency,								
AND								
Patient must have previously been issued with an authority prescription for this drug; OR								
Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.								
Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.								
The authority application must be made in writing.								
Note								
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au								
Applications for authority to prescribe should be forwarded to:								
Department of Human Services								
Prior Written Approval of Complex Drugs								
Reply Paid 9826								
GPO Box 9826								
HOBART TAS 7001								
10087X	sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets	6	5	..	*5306.74	37.70	Kuvan	SG
TESTOSTERONE UNDECANOATE								
Authority required								
Androgen deficiency in males with established pituitary or testicular disorders								
Authority required								
Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men)								
Authority required								
Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age								
10205D	testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL vial	1	1	..	147.75	37.70	Reandron 1000	BN

